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No. 05-608

Supreme Court, U.S.
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IN THE
Supreme Court of the United States

MEDIMMUNE, INC.,
Petitioner,
v.
GENENTECH, INC. and CITY OF HOPE
Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF FOR RESPONDENT CITY OF HOPE

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QUESTION PRESENTED

When a patent licensee maintains its good standing under its license in order to preserve its immunity from suit by the patent owner, may the licensee nonetheless obtain judicial advice regarding the validity and enforceability of the licensed patent to help it decide whether or not to repudiate its contractual royalty obligations, while at the same time holding the patent owner to its side of the bargain?

LIST OF PARTIES

Petitioner MedImmune, Inc. was the only plaintiff and appellant in the courts below. City of Hope, Genentech, Inc., and Celltech R&D, Ltd. were the defendants-appellees. City of Hope and Genentech are the only Respondents in this Court, because Petitioner did not seek review of the Court of Appeals' ruling concerning Celltech.

RULE 29.6 DISCLOSURE

Respondent City of Hope is a California non-profit public benefit biomedical research, treatment and educational institution. City of Hope has no parent company. No entity owns stock in City of Hope.

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STATUTES INVOLVED

Relevant constitutional and statutory provisions are set out in the Statutory Addendum to this brief.

STATEMENT OF THE CASE

MedImmune entered into a patent license in which it agreed to pay royalties in exchange for immunity from being sued for infringement. Then MedImmune itself sued in order to escape its royalty obligations under the license, but continued to claim the benefit of the license for itself as a shield against an infringement suit. The law does not permit patent licensees to exploit their licenses in this way. MedImmune's action is barred by Article III because its continued maintenance of the license as a shield against suit prevents a ripe and actionable controversy from arising. In addition, under long-standing rules of equity – which govern the exercise of declaratory judgment jurisdiction – a licensee may not attack the validity of a patent unless it first surrenders the benefits of the license by repudiation, thereby placing the parties on a level playing field.

A. Factual Background

The Cabilly II Patent. Respondent City of Hope is a California-based nonprofit organization known for its National Cancer Institute-designated Comprehensive Cancer Center and ground-breaking biomedical research. City of Hope employs more than 300 physicians and scientists who work to find the causes of and cures for cancer and other life-threatening diseases, including diabetes and HIV/AIDS. In the early 1980s, City of Hope and respondent Genentech, Inc. worked collaboratively on research developing recombinant DNA technology. J.A. 109 ¶21, 417, 485, 509. The collaboration resulted in several pioneering technologies for the production of immunoglobulins and engineered immunoglobulin chains, including techniques that are now

used in the biotechnology industry to engineer and produce life-saving therapeutic antibodies.

City of Hope and Genentech sought patent protection for these breakthroughs. On April 8, 1983, Genentech filed a patent application with the Patent and Trademark Office ("PTO") on behalf of itself and City of Hope (the "Cabilly I Application"). J.A. 109 ¶ 21, 485. The application disclosed at least two sets of inventions: one relating to engineering techniques to produce chimeric heavy or light immunoglobulin chains ("chimeric chains"); the other relating to techniques for coexpressing heavy and light immunoglobulin chains in the same cell to produce assembled immunoglobulins ("coexpression").

On November 14, 1984, another company, Celltech R&D Ltd., filed an application with the PTO relating to the coexpression technology. J.A. 276-80, 459. Celltech's application claimed priority based on a British patent application filed just two weeks before the Cabilly I Application, on March 25, 1983. J.A. 276-80, 459. Under rules then in effect, Celltech's application was confidential and not disclosed to Genentech or City of Hope.

On June 10, 1988, Genentech filed a new application as a "continuation" of the Cabilly I Application, *i.e.*, one based on the same disclosure in Cabilly I but adding new claims (the "Cabilly II Application"). *See* J.A. 47 ¶ 23. As a continuation, the Cabilly II Application is entitled to the same priority date as Cabilly I. 35 U.S.C. § 120.

On March 28, 1989, the PTO granted the Cabilly I Application and issued U.S. Patent No. 4,816,567, which covers the chimeric chain technology (the "Cabilly I Patent"). J.A. 485. On the same day, the PTO also granted Celltech's application and issued U.S. Patent No. 4,816,397 (the "Boss Patent"). J.A. 459.

Genentech recognized that the Boss Patent's claims covered the coexpression technology disclosed but not claimed in the earlier-filed Cabilly I Application. Accordingly, to provoke an "interference" proceeding in which the PTO and the courts could determine which company could properly claim inventorship, Genentech amended the claims of its pending Cabilly II Application to match the claims of the issued Boss Patent. J.A. 278; *see also* J.A. 345 (copying claims is "the permitted and standard procedure for provoking an interference").

The PTO's Board of Patent Appeals and Interferences ("BPAI") then declared an interference between the Boss Patent and the Cabilly II Application in order to determine which party had priority to the invention, *i.e.*, which party's action triggering patent protection occurred first. 35 U.S.C. § 135(a); *Cabilly v. Boss*, 55 U.S.P.Q.2d 1238 (Bd. Pat. App. & Interf. 1998); J.A. 109. In general, the first party to conceive of an invention and reduce it to practice is entitled to priority – not the first party to file a patent application. 35 U.S.C. §102(g)(2); *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 61 (1998). Genentech and Celltech diligently litigated that issue, but for unexplained reasons the BPAI did not issue its decision for more than six years after the parties submitted their papers, and more than four years after oral argument. The BPAI found that Genentech had not met its evidentiary burden of establishing earlier conception and reduction to practice. *Cabilly*, 55 U.S.P.Q.2d at 1256.

Genentech challenged the BPAI's ruling by filing a civil interference action against Celltech in federal court. *See* 35 U.S.C. § 146. Parties in such a case may introduce evidence not submitted to the BPAI. *Id.* While the case was pending, Genentech located a draft application for Cabilly I from February 1983 – a month before Celltech's British application. J.A. 281-323; *see* J.A. 272-73 ¶¶ 4-5, 325-29. The draft application is a lengthy and detailed description of

the inventions and showed that City of Hope and Genentech had priority over Celltech. J.A. 281-323.

Relying on this new and persuasive evidence, Genentech moved for summary adjudication, J.A. 273 ¶ 9, but the court strongly encouraged the parties to settle the matter with the help of a mediator, J.A. 331-33; *see also* Pet. App. 3a. In the resulting settlement, which the district court approved as a consent judgment, Celltech conceded that City of Hope's and Genentech's application had priority over the Boss Patent. J.A. 345-46; *see* J.A. 274 ¶¶ 12-13, 345-46 ¶¶ 9-10. The PTO then independently reviewed the pending claims of the Cabilly II Application, concluding that they were valid.[1] Thus, on December 18, 2001, after suffering years of administrative and litigation delay, City of Hope and Genentech finally obtained U.S. Patent No. 6,331,415B1 (the "Cabilly II Patent"). J.A. 509-50; *see also* J.A. 551 (certificate of correction listing City of Hope as co-assignee). Under applicable law, Cabilly II's term runs for 17 years from issuance. *See* 35 U.S.C. § 154 (1994).

Genentech uses Cabilly II's technologies in five of its products, including treatments for breast and colorectal cancer. City of Hope uses revenue from the licensing of the

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[1] Although the district court ordered the PTO to cancel the Boss Patent and issue Cabilly II, the PTO did not carry out these parts of the order. The PTO gave conclusive effect to the court's judgment *only* on the issue of Cabilly II's priority over Boss. The PTO independently ensured that Cabilly II satisfied all other requirements for patentability. J.A. 347-48; *Cabilly v. Boss*, 60 U.S.P.Q.2d 1752 (Bd. Pat. App. & Interf. 2001).

The United States also asserts – without citation – that the parties' settlement gave Celltech the right to share in all royalties Genentech receives on the Cabilly II Patent. U.S. Br. 4-5 n.3. That is wrong. Celltech only received a share of the royalties for a limited period of time (that has now ended), and its share was substantially lower than what it would have received under its Boss Patent but for the settlement. *See* Fed. Cir. J.A. 1713-44.

patent to support its nonprofit basic and biomedical research programs.

MedImmune's License. Petitioner MedImmune, Inc. produces its product Synagis using the method disclosed in both Cabilly patents and claimed in Cabilly II. *Compare* MedImmune Br. 2-3 (describing how Synagis is made), *with id.* at 4-5 (describing claims of Cabilly II in same terms).

While the interference between Genentech and Celltech was pending, MedImmune sought and received licenses from both companies to ensure that Synagis would not infringe regardless of which company had priority. *See* J.A. 134 ¶ 122. On June 4, 1997, MedImmune obtained its license from Genentech (acting on behalf of itself and City of Hope) under the Cabilly I Patent and "any patent issuing based on" the Cabilly II Application. J.A. 399. The license thus expressly contemplated that Genentech might receive a patent within the scope of Cabilly II. The entire reason MedImmune obtained the license for "any patent" based on the Cabilly II Application was to insure that it could not be sued for infringement if a patent issued on that application.

In addition to authorizing MedImmune to use the methods covered by the patents, the license grants MedImmune "co-exclusive" rights, in that Genentech could grant no more than four additional licenses for the same field and territory. J.A. 401. By taking the license at an early stage, MedImmune also locked in a favorable royalty rate reflecting at least two contingencies: MedImmune's product Synagis was still in development and had not been approved by the FDA, *see* Fed. Cir. J.A. 3311 (initial license fee is higher for products further in development), and Genentech and City of Hope had not received the Cabilly II Patent. MedImmune also obtained a most-favored licensee guarantee and the right to terminate the license for any reason with six months' notice. J.A. 405, 409.

In the license, MedImmune agreed to pay royalties when it practices claims of the licensed patents "which have neither expired nor been held invalid by a court or other body of competent jurisdiction from which no appeal has been or may be taken." J.A. 399, 406.[2] The background law against which the parties contracted also gives MedImmune an unconditional right to repudiate the license, stop paying royalties, and then assert patent invalidity as a defense in a lawsuit for post-repudiation damages. *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969). However, under Federal Circuit law in effect at the time the license was executed, "a licensee . . . cannot invoke the protection of the *Lear* doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid." *Studiengesellschaft Kohle, m.b.H. v. Shell Oil Co.*, 112 F.3d 1561, 1568 (Fed. Cir. 1997). Nothing in the license purports to contract around that rule to allow MedImmune to challenge the patent while claiming the benefit of the license.

The Parties' Dealings Under the License. In 1999, Genentech sought royalties from MedImmune for Synagis under the Cabilly I Patent. J.A. 414-15. MedImmune refused, asserting that Synagis fell outside the scope of Cabilly I. J.A. 416. Genentech accepted that response and took no action against MedImmune. MedImmune never paid royalties under Cabilly I, which is not at issue here. J.A. 388.

On January 7, 2002, after the Cabilly II Patent issued, Genentech sought royalties from MedImmune on sales of Synagis under Cabilly II. J.A. 419-20. In its response, dated February 13, 2002, MedImmune did not dispute that royalties

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[2] MedImmune truncates its quotation of this term of the license to create the false impression that the license contemplates that the patents' validity is an open question even in the absence of a final and unappealable judgment of invalidity. Pet'r Br. 4.

were due or raise any specific questions as to validity, enforceability, or infringement. It stated merely that "it would be helpful if you could please advise us as to your basis for believing that MedImmune's product would infringe any valid claim of the [Cabilly II] Patent such that royalties would be due." J.A. 421. The letter went on to request *additional* licenses under the Cabilly II Patent for other products MedImmune wanted to develop. J.A. 422.

Two weeks later, before Genentech responded, MedImmune commenced royalty payments. J.A. 426. A few days after that, MedImmune faxed a letter asserting that its payment was "under protest" – without indicating the nature or basis of the "protest." J.A. 426. Two weeks later, Genentech replied to MedImmune, explaining its understanding that Synagis falls within the scope of the Cabilly II Patent, but asking MedImmune (if it disagreed) to explain the process MedImmune uses to manufacture Synagis "so that we may reevaluate our position." J.A. 428. As this response shows, Genentech understood MedImmune's "protest" as relating to whether MedImmune uses the method claimed in Cabilly II in producing Synagis, just as MedImmune had earlier (successfully) contended that it did not use the method claimed in Cabilly I.

At no point did MedImmune state that it believed Cabilly II was invalid or unenforceable. Instead, MedImmune continued to press for additional licenses to cover more products it had in the pipeline. J.A. 431. MedImmune emphasized that "Genentech's licensing policy with respect to the [Cabilly II] patent has the potential to be a significant factor in MedImmune's research and development strategies." J.A. 431. In the subsequent negotiations for the additional licenses (*see* J.A. 433-35), MedImmune had the opportunity to raise arguments about validity, enforceability, or any other patent issue that could affect the royalty rate or other licensing terms. But MedImmune raised no such

issues, and it received licenses for seven more product lines in January 2003 – more than a year after Cabilly II issued and MedImmune became fully aware of the patent's claims and prosecution history. J.A. 108, 134, 437-453.

B. Procedural History

District Court Proceedings. Less than three months after it had secured its position with its new licenses, MedImmune filed this lawsuit seeking, *inter alia*, declaratory judgments that the Cabilly II Patent is invalid and unenforceable. J.A. 1, 41.[3] At all times relevant to this case, however, MedImmune has sought to retain the benefits of its license for Synagis by continuing to pay royalties. J.A. 389. Yet it inflicted on City of Hope and Genentech the precise burden the license was intended to avoid – patent litigation.[4]

In its first responsive pleading, City of Hope asserted nonjusticiability defenses to these claims. J.A. 222 ¶¶ 8, 10. Initially, however, the district court proceedings focused on antitrust claims that MedImmune had asserted against Genentech and Celltech (but not City of Hope). *See* J.A. 141-46. After the district court dismissed the antitrust counts on the merits, J.A. 349-71, Genentech and City of Hope moved to dismiss MedImmune's declaratory claims as nonjusticiable. J.A. 382-83, 384. The court granted the motions under *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004). Pet. App. 21a-31a; J.A. 436.

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[3] As set forth more fully in Genentech's brief, MedImmune's complaint does not allege any basis for claiming that the production of Synagis is not covered by the license, *i.e.*, does not use the technique claimed in Cabilly II. Rather, MedImmune artfully pleads its purported contract and infringement claims to incorporate the patent validity and enforceability issues that are the focus of its complaint. *See* J.A. 115-30, 136-41.

[4] MedImmune has made this "license and sue" tactic its standard practice. *See, e.g., MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376, 1378 (Fed. Cir.), *petition for cert. filed*, 74 U.S.L.W. 3336 (U.S. Nov. 22, 2005) (No. 05-656).

Federal Circuit Appeal. The Federal Circuit affirmed, concluding that MedImmune's declaratory claims do not present a justiciable controversy because "MedImmune is complying fully with the license terms and cannot be sued by the patentee[s]." Pet. App. 5a. The court rejected MedImmune's reliance on *Lear v. Adkins* because, in sharp contrast to that case, "MedImmune is paying the license royalties; and . . . Genentech has no ground on which to cancel the license or otherwise bring suit affecting the licensed subject matter." Pet. App. 5a. The court stressed "the inequity [that would result] when the patent owner, having contracted away its right to sue, is in continuing risk of attack on the patent whenever the licensee chooses – for example, if the product achieves commercial success – while the licensee can preserve its license and royalty rate if the attack fails. This imbalance distorts the equalizing principles that underlie the Declaratory Judgment Act." Pet. App. 7a. Given that "MedImmune avoided and continues to avoid" taking actions that would create a justiciable controversy, the Federal Circuit held that Article III's requirements had not been met. Pet. App. 8a.[5]

Administrative Reexamination. The PTO is presently reexamining the Cabilly II Patent in two *ex parte* proceedings under 35 U.S.C. §§ 301-305. MedImmune anonymously initiated one of these proceedings after petitioning this Court for certiorari but before filing its reply at the certiorari stage. *See* Pet'r Br. 48 n.18. MedImmune did not disclose its pending reexamination request to the Court at that time. To date, the PTO has issued an initial office action rejecting the claims of Cabilly II. Such initial rejections are an ordinary part of the back-and-forth between the PTO and patentees, however, similar to the process on initial patent applications,

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[5] The court also affirmed dismissal of MedImmune's antitrust claims, Pet. App. 2a, and MedImmune did not seek review of that ruling in this Court.

and are not good indicators of the ultimate outcome.[6] In 88% of cases, a patent subject to *ex parte* reexamination survives in whole or part. *See* Wayne O. Stacy, *Reexamination Reality*, 66 Geo. Wash. L. Rev. 172, 182-83 (1997).

SUMMARY OF ARGUMENT

1. Because MedImmune's license bars any suit by Genentech and City of Hope, and because MedImmune lacks any right of action for affirmative relief against Respondents, there is no ripe justiciable controversy here. Article III extends the federal judicial power to cases or controversies in law and equity – categories whose parameters are informed by the historical business of Anglo-American courts. The Declaratory Judgment Act ("DJA"), 28 U.S.C. § 2201 *et seq.*, did not expand that jurisdiction or create new substantive rights. It simply provided a new procedure for obtaining adjudication of controversies already within the courts' preexisting jurisdiction. Hence, there must already be a ripe controversy cognizable in law or equity for there to be a ripe controversy for declaratory relief.

Within these bounds, the declaratory procedure performs important functions. In a "mirror-image" declaratory suit, the DJA allows the party who would be the defendant in a conventional suit to take the initiative as plaintiff and sue for a declaration of nonliability – but only if the declaratory defendant presently has a ripe claim for conventional relief. Such a declaratory suit is simply the mirror image of a ripe conventional controversy. The DJA also allows the plaintiff in a conventional suit to seek declaratory relief in addition to,

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[6] *See Lear*, 395 U.S. at 658 (describing typical procedure of rejections by PTO and responses by applicant); 35 U.S.C. § 305 (extending initial examination procedures to reexamination); Patent & Trademark Off., Dep't of Commerce, *Manual of Patent Examining Procedure* § 706.02(b) (8th ed. 2005) (providing that PTO rejection can be overcome by argument for rejected claim or by amendment of claim).

or instead of, conventional relief. For example, in a suit for a declaration that a law is unconstitutional, there is a justiciable controversy because the plaintiff already has a ripe claim for an injunction under *Ex parte Young* and § 1983.

But this Court has *never* approved a declaratory suit when no claim for conventional relief is ripe. Undoubtedly, obtaining advice about whether contemplated conduct would result in liability is desirable, but giving such advice in advance of actual or imminent conduct is the role of legal counsel, not courts.

Under these principles, there is no ripe controversy here. In stark contrast to mirror-image cases like *Altvater* and *Cardinal*, MedImmune's good standing as a licensee bars Genentech and City of Hope from bringing suit for patent infringement or breach of license. And MedImmune itself lacks any affirmative right of action which would allow it to seek a declaration as an alternative to conventional relief. There would be a ripe justiciable controversy only *if* MedImmune breached or repudiated its license – a contingency that may never occur, since MedImmune's avowed aim is to maintain the license as a shield against suit.

2. Dismissal is also proper on prudential jurisdictional grounds, which this Court may address in the first instance without ruling on the Article III issue – an approach favored by the doctrine of constitutional avoidance. Jurisdiction under the DJA is inherently discretionary and equitable. And under the centuries-old equitable rule of licensee estoppel, MedImmune may not keep the benefits of its license and at the same time attack the validity of the underlying patent in order to escape its license obligations. This kind of one-sided suit is inherently inequitable, because the patentee remains bound by the license and its compromise royalty rate if the attack fails, but the licensee is freed from paying the royalties if it succeeds. Equity demands that the licensee repudiate the license before seeking to invalidate the licensed

patent, thereby maintaining a level playing field between the patentee and the licensee.

Lear is consistent with that equitable rule, because the licensee there had repudiated its license before attacking the validity of the underlying patent in court. And, with at most a few scattered exceptions immediately after *Lear*, no court has ever allowed a suit in the present posture. From its creation, moreover, the Federal Circuit has consistently recognized that a licensee cannot attack a patent while keeping the benefits of its license – a rule reaffirmed in *Studiengesellschaft* before the parties entered into the license here.

The question is thus whether a long-standing rule of equity should be abandoned now to allow MedImmune to bring a virtually unprecedented lawsuit. Even if justified by policy considerations, any such change should come from Congress, not the Court. Moreover, policy considerations favor no such change. MedImmune's proposal would seriously impair the core purposes of patent law: to provide incentives for the invention, disclosure, and dissemination of new technologies. Under the MedImmune rule, patentees would have little incentive to enter into one-sided license agreements or (as the United States concedes) would demand exorbitant upfront royalties that would deter technology transfer and raise prices for consumers. That impairment of efficient licensing incentives cannot be justified by an asserted need to free licensees to challenge invalid patents, because the traditional equitable rule and *Lear* already allow such challenges after repudiation. MedImmune's "policy" argument rests on the misconception that the only goal of our patent system is to encourage litigation about patent validity, rather than to provide incentives for innovation. There is no basis here for disturbing settled expectations by permitting a novel, aggressive, and one-sided lawsuit like this.

ARGUMENT

I. MedImmune Is Seeking an Advisory Opinion About a Hypothetical Controversy That Is Not Ripe.

A. There Must Be A Ripe Claim in Law or Equity Before the Declaratory Procedure May Be Used.

There is no justiciable controversy for declaratory relief here, because none of the parties can presently bring an action for conventional legal or equitable relief. The DJA did not expand the subject-matter jurisdiction of the federal courts. *Skelly Oil Co. v. Phillips Petrol. Co.*, 339 U.S. 667, 671-72 (1950). Rather, "the operation of the Declaratory Judgment Act is procedural only," *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937), and "merely allow[s] the resolution of a 'case or controversy' in an alternative format." *Calderon v. Ashmus*, 523 U.S. 740, 747 (1998). Hence, the DJA did not accelerate the point at which a controversy becomes ripe for judicial intervention. It must be ripe under the same Article III standards that have always applied to conventional suits.

Article III extends the "judicial Power" to "Cases, in Law and Equity." U.S. Const. art. III, § 2. To the Framers "'[a] case in law or equity ... was a term ... of limited signification.'" *DaimlerChrysler Corp. v. Cuno*, 126 S. Ct. 1854, 1861 (2006) (quoting 4 Papers of John Marshall 95 (C. Cullen ed. 1984)). The Court has "always taken this to mean cases and controversies of the sort traditionally amenable to, and resolved by, the judicial process," *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102 (1998), or "matters that were the traditional concern of the courts at Westminster and only if they arose in ways that to the expert feel of lawyers constituted 'Cases' or 'Controversies.'" *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 774 (2000) (quotation marks omitted). Under traditional legal and equitable principles, a controversy is not ripe for

adjudication until an alleged invasion of a legally protected interest has actually occurred, or is at least imminent. *See, e.g., McConnell v. FEC*, 540 U.S. 93, 225-26 (2003). That limitation flows from the very nature of "Cases, in Law and Equity." A legal controversy is generally ripe only after one party has actually invaded the other's legally protected interests, such that an action for damages or other remedy at law lies. Equity extends the judicial power further, to encompass situations when such invasion is imminent – *i.e.*, "certainly impending." *DaimlerChrysler*, 126 S. Ct. at 1863; *McConnell*, 540 U.S. at 225-26. *See generally Woodworth v. Stone*, 30 F. Cas. 593, 594 (C.C.D. Mass. 1845) (Story, J.).[7] But a "claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998) (quotation marks omitted). Such a controversy is merely "hypothetical" and not "appropriate for judicial determination." *Aetna*, 300 U.S. at 240.

Consistent with these principles, a controversy is appropriate for resolution in a declaratory action when it has ripened to the point where a conventional suit in law or equity could be brought by one or the other of the parties. Thus, this Court has *never* approved a declaratory suit when there is not a ripe non-declaratory legal or equitable controversy within the meaning of Article III. To the contrary, in its decisions upholding the constitutionality of the declaratory procedure, the Court has emphasized that the DJA simply provides an alternative means of adjudicating disputes that are already within the federal courts' jurisdiction, in one of two ways: either the declaratory judgment defendant has a current right to bring a

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[7] As Justice Story explained, a bill *quia timet* is consistent with these requirements because it requires proof of an "intended violation." *Id.*; *accord Fletcher v. Bealey*, L.R. 28 Ch. D. 688, 698 (1884) ("There must, if no actual damage is proved, be proof of imminent danger . . .").

conventional suit for non-declaratory (legal or equitable) relief, or the declaratory plaintiff has a current right to do so.

1. The Potential Defendant to a Ripe Conventional Suit Can File a Mirror-Image Suit for a Declaration of Nonliability.

An important benefit of the declaratory procedure is that it levels the playing field by "allowing prospective defendants to sue to establish their nonliability." *Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 504 (1959). Before the DJA, a person with alleged liability was powerless to obtain adjudication of a dispute if he did not have his own claim for coercive relief. He was at the mercy of the potential plaintiff, who could sue at any time but might not do so for tactical reasons. The DJA eliminated that one-sidedness by allowing the prospective defendant to turn the tables and initiate a suit for a declaration of nonliability.

Aetna exemplifies this kind of "mirror-image" suit. Aetna repeatedly refused to pay insurance claims on the ground that the relevant policies had lapsed. 300 U.S. at 238-39. But the insured did not sue Aetna, so Aetna filed its own action for a declaration that it was not liable. *Id.* at 239. In upholding the declaratory suit, the Court emphasized that the insured presently had ripe conventional claims both for monetary relief and for an equitable decree of nontermination in light of Aetna's repudiation. *Id.* at 243-44. Thus, Aetna was seeking "an adjudication of *present right* upon established facts." *Id.* at 242 (emphasis added). The Court explained that "the character of the controversy and the issue to be determined is essentially the same whether it is presented by the insured or the insurer. . . . It is the nature of the controversy, not the method of its presentation or the particular party who presents it, that is determinative." *Id.* at 244. *Aetna* thus made clear that justiciable controversies are symmetrical, such that Congress could authorize mirror-image suits. But the DJA did not render controversies ripe

and justiciable at any earlier point than for conventional actions.

MedImmune (and the United States) nonetheless argue that *Maryland Casualty* found a declaratory suit justiciable when no conventional suit was ripe. That is incorrect. *Maryland Casualty* actually reiterated *Aetna*'s holding that even where "the declaratory judgment suit" reverses "the positions of the parties in the conventional suit," the Article III "inquiry is the same in either case." *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941). Consistent with that principle, the declaratory defendant in *Maryland Casualty* did have ripe conventional claims against the declaratory plaintiff. The case involved the recurring fact pattern in which an injured person sues an insured but not its insurer, and then the insurer brings a declaratory action against both the injured person and the insured to determine whether the insurer has an obligation to defend and pay any judgment. *Id.* at 271-72. That is the mirror image of the ripe affirmative suit that an injured party could *presently* bring under federal procedure against both the insured and its insurer. *See* Fed. R. Civ. P. 18(b) (permitting joinder of insurer as defendant before adjudication of insured's primary liability); *see also* Fed. R. Civ. P. 14 (impleader procedure).[8] Thus, there was a ripe conventional controversy in *Maryland Casualty*. The Court therefore allowed the mirror-image suit under the DJA and, indeed, emphasized that the "inquiry is

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[8] In finding a ripe controversy, *Maryland Casualty* followed *United States Fidelity & Guaranty Co. v. Pierson*, 97 F.2d 560 (8th Cir. 1938) (cited 312 U.S. at 273), which explained that the injured party has a ripe conventional claim against the insurer because the insurer's liability *vel non* depends only on actually existing facts and, indeed, the insurer is the real party in interest in the injured party's suit against the insured. 97 F.2d at 562. MedImmune's misreading of *Maryland Casualty* is based on the *state procedure* that prevented the injured party from immediately suing the insurer in state court. But state procedures are not controlling under the DJA. *Skelly Oil*, 339 U.S. at 673-74.

the same" in conventional and declaratory suits. 312 U.S. at 273.

2. A Plaintiff with a Ripe Conventional Claim Can Seek a Declaration as Alternative Relief.

Not all declaratory actions are the mirror images of conventional suits. A ripe controversy also exists when the declaratory *plaintiff* can presently sue for a coercive judgment, but chooses to seek declaratory relief instead of, or in addition to, seeking money damages or an injunction. In such "alternative relief" actions, the case or controversy arises from an actual or imminent invasion of the plaintiff's own legal interests, rather than from an invasion of the defendant's interests as in a mirror-image declaratory action.

Suits for declarations that laws are unconstitutional, such as *Steffel v. Thompson*, 415 U.S. 452 (1974), are justiciable on this "alternative relief" basis. Controversies of this kind are ripe because the declaratory plaintiff can presently bring a conventional action to enjoin enforcement of the unconstitutional law. The plaintiff may therefore use the declaratory procedure to seek a declaration of unconstitutionality as an alternative to injunctive relief. The Court emphasized this in its first decision upholding the declaratory procedure, in a suit for a declaration that a state tax unconstitutionally burdened interstate commerce. *Nashville, Chattanooga, & St. Louis Ry. v. Wallace*, 288 U.S. 249 (1933). In his opinion for a unanimous Court, Justice Stone framed the issue thus:

> [T]he narrow question presented for determination is whether the controversy before us, which would be justiciable in this Court if presented in a suit for injunction, is any the less so because through a modified procedure appellant has been permitted to present it . . . without praying for an injunction . . . .

Id. at 262-63. So framed, the answer was clear: the form of relief did not affect the ripeness of the suit. *Id.* at 263.

The Court made the same point in *Steffel*, which stressed that declaratory relief against unconstitutional laws is simply an alternative to injunctive relief under *Ex parte Young*, 209 U.S. 123 (1908), pursuant to the right of action created by Congress in 42 U.S.C. § 1983. *Steffel*, 415 U.S. at 464-66. *Steffel* also reiterated the settled doctrine, which can be traced back at least to *Young* itself, that this equitable jurisdiction exists even if the plaintiff complies with the law to avoid prosecution. In that situation, the official's threat to enforce the unconstitutional law is a *present* invasion of the plaintiff's own legally protected rights, analogous to trespass, which creates a ripe controversy regardless of whether the plaintiff complies with the law or defies it. *Young*, 209 U.S. at 155-56, 158, 167; *Steffel*, 415 U.S. at 459 (where person complies with unconstitutional law to avoid prosecution, threat of enforcement "deters the exercise of his constitutional rights"); *Lake Carriers' Ass'n v. MacMullan*, 406 U.S. 498, 508 (1972) (when "compliance is coerced by the threat of enforcement, ... the controversy is both immediate and real").[9] In these cases, then, declaratory relief is simply an alternative "to the strong medicine of the injunction." *Steffel*, 415 U.S. at 466-68 & n.18; *see* S. Rep. No. 73-1005, at 3 (1934).[10]

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[9] Likewise, pre-enforcement review of agency regulations is justiciable under the Administrative Procedure Act when "the expected conformity to them causes injury cognizable by a court of equity." *Abbott Labs. v. Gardner*, 387 U.S. 136, 150 (1967) (quotation marks omitted).

[10] The existence of equity *jurisdiction* in these cases does not mean an injunction would necessarily be granted *on the merits*. Because declaratory relief is less intrusive, it may be available when an injunction is denied on the merits, such as when the imminent injury to the plaintiff's rights is not irreparable or an injunction would undermine comity. *Nashville*, 288 U.S. at 264; *Steffel*, 415 U.S. at 468-73. But as in any other case in which relief is denied on the merits, the denial of

MedImmune (and the United States) fundamentally misread cases like *Steffel* as if they were mirror-image declaratory actions like *Aetna*. From that false perspective, they argue that such controversies are ripe merely because the *defendant* government official *would be able to* bring an enforcement action against the declaratory plaintiff *if* the plaintiff defied the law – which they analogize to Genentech's and City of Hope's hypothetical ability to sue MedImmune if MedImmune repudiated its license. But as Justice Stone explained more than 70 years ago, these constitutional challenges are justiciable because the plaintiff can presently sue for traditional equitable relief, *Nashville*, 288 U.S. at 263, not because of any hypothetical suit that the defendant might be able to bring under conditions that have not and may never come to pass. Properly understood, *Steffel* cannot be analogized to this case because MedImmune, as plaintiff, lacks a ripe claim for conventional relief against Respondents. *Infra* at 25-29.

3. MedImmune's Reliance on Lower Court Decisions and Legislative History Is Misplaced.

Ignoring this Court's admonishments that the Article III inquiry is identical regardless of whether declaratory or conventional relief is sought, MedImmune (and the United States) cite lower court cases which they characterize as allowing declaratory actions for interpretations of contracts in advance of breach, repudiation, or other actual or imminent conduct that would ripen a conventional contract suit. Initially, the impression Petitioner tries to create that such cases are legion does not correspond to reality. Contract cases (other than insurance coverage disputes like

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injunctive relief is irrelevant to whether there is a justiciable controversy in the first place. By the same token, a declaratory action would never be an available alternative in situations where an injunctive suit is barred on ripeness grounds – such as when the plaintiff wants to challenge the constitutionality of a law that is not enforced.

Aetna and *Maryland Casualty*) represent a small fraction of the declaratory suits filed in federal court, presumably because such cases are governed by state law and federal jurisdiction ordinarily is lacking, *Skelly Oil*, 339 U.S. at 671-74.[11] To the extent declaratory contract cases are filed in federal court, many are in fact justiciable under the traditional Article III standards described above. Indeed, even after cherry-picking the lower court decisions that most closely favor its own theory, MedImmune cites several cases that do not support its position because there were ripe claims for conventional relief at the time declaratory relief was sought. *E.g.*, *Duane Reade Inc. v. St. Paul Fire & Marine Ins. Co.*, 411 F.3d 384, 387 (2d Cir. 2005) (cited at Pet'r Br. 20) (plaintiff had ripe conventional claim for breach of insurance policy); *NUCOR Corp. v. Aceros y Maquilas de Occidente, S.A. de C.V.*, 28 F.3d 572, 578 (7th Cir. 1994) (cited at Pet. 15-16) (defendant had ripe conventional claims for deceptive trade practices and breach of contract); *see also infra* at 38 & note 20 (discussing patent license cases).

To be sure, there are some other cases where lower courts have adjudicated declaratory claims in the absence of a ripe conventional controversy under Article III. But MedImmune cannot cite a single case in which *this Court* has allowed a declaratory suit in such circumstances. The reason is clear: a suit to find out whether a party *would* breach its contract *if* it engaged in certain conduct inherently seeks legal advice about facts that are hypothetical, not actual or imminent – "contingent future events that may not occur as anticipated,

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[11] Thus, these cases can be heard in state court if the state law that governs them provides for such resolution. If not, it is hard to see what harm is done by keeping state law cases that cannot be heard in state court out of federal court too. *See, e.g., 118 E. 60th Owners, Inc. v. Bonner Props., Inc.*, 677 F.2d 200, 204-06 (2d Cir. 1982) (cited at Pet'r Br. 20) (declining jurisdiction over declaratory claim governed by state law where precluded by state procedure).

or indeed may not occur at all." *Texas*, 523 U.S. at 300 (quotation marks omitted). Undoubtedly, obtaining advice about whether contemplated conduct would result in liability is desirable, but giving such advice in advance of decisions about whether to breach is the role of legal counsel, not courts. Though lower courts may have sometimes allowed declaratory suits about hypothetical or contemplated conduct when no conventional suit could be brought, this Court has never crossed that threshold and should not do so now.

In fact, this case is a particularly poor candidate for even considering adjudication of hypothetical rights based on MedImmune's assertion that it is burdened by having to decide whether to repudiate the license before knowing for certain the legal status of the Cabilly II Patent. Assuming *arguendo* that such prudential considerations could *expand* the jurisdiction of federal courts beyond the historical parameters encapsulated in Article III, MedImmune's suit still could not be allowed. As Genentech shows in its brief, this suit is fundamentally different from declaratory suits on ordinary contracts where uncertainties about the meaning of the contract itself have arisen after it is signed. Here, the very uncertainty about which MedImmune complains was built into the terms of the deal. For that and other reasons, prudential and equitable principles require dismissal of MedImmune's claims, not their immediate adjudication. *Infra* at 32-50.

MedImmune also cites legislative history suggesting that congressional committees thought declaratory suits could be brought to interpret contracts without breach. But suits outside the scope of Article III cannot be authorized by statute – much less by legislative history. Just as importantly, MedImmune ignores Congress's overarching intent in enacting the DJA – expressed in the statute's actual language as well as the legislative history – to confine declaratory actions to "actual controvers[ies]" within Article

III's limits. 28 U.S.C. § 2201; *see* S. Rep. No. 73-1005, at 5 (1934). By expressly limiting the DJA to "actual controversies," Congress intended it to be "operative only in respect to controversies which are such in the constitutional sense," *Aetna*, 300 U.S. at 240, and so did "not attempt to change the essential requisites for the exercise of judicial power." *Ashwander v. TVA*, 297 U.S. 288, 325 (1936). That congressional intent excludes lawsuits about hypothetical circumstances, particularly where the supposed right to seek a judicial declaration is entirely asymmetrical, with the patentee barred by a license from suing the licensee. The DJA was never intended to create that kind of unfair disparity. *See Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 19 n.19 (1983) ("the declaratory remedy . . . was designed to permit adjudication of either party's claim of right").[12]

B. No Conventional Suit – and Thus No Declaratory Suit – Is Ripe Here.

Under these established principles, there is no ripe controversy here. Because MedImmune has no intention of repudiating its license, it has prevented the ripening of any suit against it for patent infringement or breach of license. Therefore MedImmune cannot bring a mirror-image declaratory action to establish that it would not be liable *if* it repudiated the license. Nor has Congress given parties like MedImmune any substantive rights whose invasion would allow MedImmune to seek a declaration as an alternative to coercive relief. As long as MedImmune remains an

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[12] The only apparent exception to the symmetry of declaratory rights of action is for suits to declare laws unconstitutional, such as *Steffel*. For prudential reasons, government officials ordinarily cannot sue in reverse to have a law declared constitutional. *See Franchise Tax Bd.*, 463 U.S. at 21 ("States are not significantly prejudiced by an inability to come to federal court for a declaratory judgment in advance of a possible injunctive suit by a person subject to federal regulation").

authorized user rather than an infringer, there can be no justiciable controversy.

1. Mirror-Image Suits Are Important in Patent Law, But Cannot Be Brought When a License Bars Any Suit by the Patentee.

Mirror-image declaratory suits play an important role in patent law. Before the DJA, a patentee could engage in the "*danse macabre*" of accusing competitors of infringement but never filing suit, thus forcing the competitors to choose between incurring a growing potential liability for infringement or abandoning their businesses. *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 95-96 (1993). The patentee might even file suit for its *in terrorem* effect, but then dismiss it prior to judgment. *See* Edwin Borchard, *Declaratory Judgments* 43, 802-08, 812-16 (2d ed. 1941). The DJA ended these strategies. If the patentee can presently sue, the potential infringer can seize the initiative with a mirror-image declaratory suit. *Cardinal*, 508 U.S. at 96; *see also Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 176 (1965) (under DJA, accused infringer "need not await the filing of a threatened suit by the patentee"). Similarly, after being sued, accused infringers can assert declaratory counterclaims to prevent unilateral dismissal by the patentee. *Cardinal*, 508 U.S. at 96.

Altvater and *Cardinal* exemplify the latter situation. In each case, the patentee first filed a conventional suit for legal or equitable relief against accused infringers, who then filed counterclaims for declarations of patent invalidity. *Altvater v. Freeman*, 319 U.S. 359, 360-61 (1943); *Cardinal*, 508 U.S. at 85-86. As the patentees had already filed conventional suits, these were plainly ripe controversies. *Cardinal*, 508 U.S. at 96 ("If . . . a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction of a complaint, or a counterclaim, under the" DJA); *Altvater*, 319

U.S. at 363 ("the issue of validity may be raised by a counterclaim in an infringement suit").[13]

Here, however, MedImmune has forestalled the ripening of any justiciable controversy through its deliberate strategy of maintaining its good standing as a licensee. This case is therefore fundamentally different from *Altvater* and *Cardinal*, where the patentees not only *could* sue, but had actually done so. MedImmune's avowed intent to maintain its license forestalls any such suit. *See Textron Lycoming Reciprocating Engine Div. v. United Auto. Workers of Am., Int'l Union*, 523 U.S. 653, 662-63 (1998) (opinion of Breyer, J.) (for mirror-image declaratory action to be ripe, actionable conduct by plaintiff must at least be imminent).[14]

MedImmune (and the United States) nonetheless argue that *Altvater* is exactly like this case because the alleged infringer there was making royalty payments to the patentee. But that ignores the essential distinction. In *Altvater* – unlike this case – the payments did not negate the patentee's claims. First, the patentee alleged that the former licensee had

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[13] *Altvater* and *Cardinal* also addressed the distinct issue of whether a declaratory counterclaim of patent invalidity becomes moot on appeal after rejection of the patentee's infringement claim – the central question in both cases. 319 U.S. at 363-64; 508 U.S. at 96. *Cardinal* made clear, however, that mootness on appeal is entirely distinct from whether there is a live controversy to support the filing of a declaratory invalidity claim in the first instance. 508 U.S. at 95-98; *cf. Friends of the Earth, Inc. v. Laidlaw Envt'l Servs. (TOC), Inc.*, 528 U.S. 167, 189-92 (2000).

[14] There is also no merit to the suggestion of some *amici* that *Respondents* could file their own declaratory suit to establish the validity of their patent. Such a suit by the patentee would simply break out a single issue relevant to the patentee's own potential cause of action for infringement, which is what this Court held a declaratory plaintiff may not do in *Calderon*, 523 U.S. at 747. Moreover, patents are presumed valid until proven otherwise, 35 U.S.C. § 282, and a court may hold only that a patent has not been proved invalid, not that it is valid. *See, e.g., Shelcore, Inc. v. Durham Indus., Inc.*, 745 F.2d 621, 627 (Fed. Cir. 1984).

breached the license in other ways, by manufacturing and selling patented products prohibited by the license. 319 U.S. at 360. Second, the license had terminated in any event. *Id.* at 362. Third, the royalties were paid under an injunction, not to maintain the protection of the (terminated) license against suit. *Id.* at 365. For these reasons, payment of royalties did not bar a suit by the patentee. Thus, the United States' attempt to liken *Altvater* to this case by asserting that the alleged infringer in *Altvater* could not be sued (U.S. Br. 18) is simply mystifying. Not only could the patentee sue in *Altvater*, it had in fact done so by initiating the litigation.

In truth, MedImmune's aggressive litigation strategy is virtually unprecedented even in the lower courts. *Infra* at 38 & note 20 (discussing cases). That is unsurprising, because in this context any potential justiciable controversy is either moot or unripe. Before the license, there could have been a case or controversy if MedImmune had actually or imminently engaged in conduct that could be infringing. But the license mooted any such potential controversy. On the other hand, a new controversy could arise if MedImmune took actions that breached the license. But such a suit is not yet ripe (and may never be). MedImmune has not taken such action and has disclaimed any intention of doing so.

2. Congress Has Not Given MedImmune Its Own Right of Action for Affirmative Conventional Relief.

It is equally clear that there is no ripe claim for legal or equitable relief that MedImmune could assert against Genentech or City of Hope, which would allow MedImmune to seek declaratory relief as an alternative to damages or an injunction. In fact, Congress has steadfastly refused to give affirmative rights of action to parties like MedImmune. MedImmune's broadsides against the Patent Act's remedial scheme and the PTO's handling of patent applications and reexaminations are nothing but blatant appeals for this Court

to second-guess Congress and supplant the executive officials it has charged with administrative functions.

Congress has vested executive officials in the PTO with the authority to examine patent applications and issue patents when the statutory requirements for patentability are met, 35 U.S.C. § 131, and authority to reexamine previously granted patents under statutorily enumerated conditions, *id.* §§ 301-318, and has also authorized the applicant or patentee to seek judicial review of denial of its application or an adverse decision on reexamination, *id.* §§ 141, 306, 315(a). Further, Congress has defined "infringe[ment]" as the act of practicing a patent "without authority," *id.* § 271(a); given the patentee a "remedy by civil action for infringement of a patent," *id.* § 281; and authorized conventional legal and equitable relief against infringers to protect that core substantive right, *id.* §§ 271, 281-285. Noninfringement, invalidity, and unenforceability are *defenses* to an infringement suit. *Id.* § 282. But, except for narrow statutory exceptions not at issue here, Congress has not created any express or implied right of action by which interested private persons who cannot be sued for infringement may test the validity or enforceability of a patent. *Mowry v. Whitney*, 81 U.S. (14 Wall.) 434, 439-41 (1872); *United States v. Am. Bell Tel. Co.*, 128 U.S. 315, 368-73 (1888); *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 65 (1973) (Rehnquist, J., dissenting); *Christianson v. Colt Indus. Oper. Corp.*, 486 U.S. 800, 808 & n.2 (1988) (Stevens, J., concurring) ("I find no merit in respondent's suggestion that we should recognize an implied cause of action" to enforce patentability requirements).[15]

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[15] The two statutory exceptions to this rule are for (1) civil interference actions initiated by one patentee or applicant against another (the procedure utilized by Genentech against Celltech, *see supra* at 3-4), 35 U.S.C. § 146; and (2) judicial review by a third-party requester of a PTO decision upholding a patent in an administrative *inter partes*

It is up to Congress – not the courts – to decide whether to create new substantive rights (something Congress did not do in the purely procedural DJA, *e.g.*, *Beacon*, 359 U.S. at 509). When Congress creates new rights, their actual or imminent invasion can give rise to a justiciable controversy where none would otherwise exist. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 580 (1992) (opinion of Kennedy, J.) ("Congress has the power to define injuries and articulate chains of causation that will give rise to a case or controversy where none existed before"). Congress has in fact exercised that power in the Patent Act as it applies to generic drugs – but not here. Congress provided that the mere filing of an application for regulatory approval to market a generic drug in advance of the expiration of a relevant patent is an act of infringement, which allows the patentee immediately to bring a suit for injunctive relief. 35 U.S.C. § 271(e)(2)-(4); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 665-67 (1990) (explaining this "artificial" act of infringement). And when a suit for infringement accrues in that situation, a mirror-image declaratory suit may also be ripe. 35 U.S.C. § 271(e)(5) (authorizing mirror-image declaratory suits in this context after 45 days). Thus, by giving patentees a new substantive right, Congress created a system for early adjudication of generic drug patent disputes when that right is invaded.

Congress also could have given patent licensees new substantive rights on which to bring suit, even absent claims against them for infringement. For example, Congress might have created a cause of action against patentees who request royalty payments where the patent is invalid – a claim that

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reexamination proceeding (which Congress did not extend to preexisting patents such as Cabilly II), *id.* § 315(b); Pub. L. No. 106-113, tit. IV, § 4608(a), 113 Stat. 1501, 1536, 1501A-572 (1999) (effective date). The narrowness of the express exceptions drives home that there is no general right of interested persons to challenge a patent.

could be ripe even if the license barred the patentee from suing. But Congress has not done so.

For that reason, this suit is fundamentally different from pre-enforcement challenges to the constitutionality of statutes like *Steffel*. Those cases involve invasion of the plaintiff's own substantive rights that the Constitution itself guarantees, and they are brought pursuant to the cause of action created by Congress in § 1983. *See supra* at 17-19. In that context, the DJA merely supplies an alternative procedure and form of relief for a suit the plaintiff could already bring to vindicate his preexisting rights. That is a far cry from the situation here, where the only substantive rights created by Congress belong to Respondents, not MedImmune, and the license negates any controversy relating to those rights.[16]

Restricting the judicial power to justiciable controversies "is crucial in maintaining the tripartite allocation of power set forth in the Constitution." *DaimlerChrysler*, 126 S. Ct. at 1861 (quotation marks omitted). That is certainly true here. Article III's requirements preserve the statutory patent regime enacted by Congress and the authority it confers on the Executive, by ensuring that the judiciary does not inject itself into a disagreement about patent validity or enforceability except when properly presented as part of fully ripe controversy suitable for judicial resolution. As this Court emphasized 140 years ago, if "an individual finds himself injured" by an allegedly invalid patent, "it is no hardship to require him" to seek relief from executive officials. *Mowry*, 81 U.S. at 441. But allowing any interested person to sue in court to invalidate the patent "would tend to discredit the authority of the government in

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[16] Nor may MedImmune leverage its justiciable (but meritless) antitrust claims to sustain its declaratory patent claims on an ancillary jurisdiction theory. The requirements of Article III must be separately satisfied for each claim in a complaint. *DaimlerChrysler*, 126 S. Ct. at 1866-68.

such matters" – and "seriously impair the value of the title which the government grants after regular proceedings before officers appointed for the purpose." *Id.*

3. "Reasonable Apprehension of Suit" Is Not at Issue Here.

Consistent with the foregoing, the Federal Circuit correctly reasoned that this suit is not ripe because "MedImmune is complying fully with the license terms and cannot be sued by the patentee[s]." Pet. App. 5a. Unfortunately, the Federal Circuit then confused matters by invoking "reasonable apprehension of suit." *Id.* at 7a-9a. The impossibility of the patentee suing negates any justiciable controversy. It is thus unnecessary to inquire whether, in addition, the licensee also has a "reasonable apprehension" of being sued.

This is made clear by considering both prongs of the Federal Circuit's test for the ripeness of declaratory suits: "First, the plaintiff must actually produce or be prepared to produce an allegedly infringing product. Second, the patentee's conduct must have created an objectively reasonable apprehension on the part of the plaintiff that the patentee will initiate suit if the activity in question continues." *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811 (Fed. Cir. 1996); *see also* Pet. App. 7a. The first prong of this test goes to the justiciability requirement at issue here: whether the declaratory plaintiff is actually or imminently engaging in allegedly infringing conduct, which allows the patentee to bring an infringement suit now. If not, there is no ripe controversy, and the inquiry is at an end. The second prong relating to "reasonable apprehension" comes into play only as an additional requirement if the potential infringer can be sued under the first prong. *See, e.g.*, *EMC*, 89 F.3d at 811. As the first prong is not satisfied here, "reasonable apprehension" is irrelevant.

The briefs of MedImmune and its *amici* nonetheless brim with critiques of the Federal Circuit's application of the "reasonable apprehension" prong in cases where the patentee *can* sue, but refuses to do so. These arguments might well raise questions that merit the Court's attention in some future case where they are presented – although there are certainly counterarguments.[17] But those questions are not presented here. This case has nothing to do with scenarios in which the patentee refuses to sue for strategic reasons, or makes veiled threats of suit that do not create a "reasonable apprehension" under the Federal Circuit's application of its standard. There is no ripe controversy here because MedImmune has deliberately precluded Respondents from suing – not because of any strategic conduct by Genentech or City of Hope.

C. This Suit Also Is Not Justiciable Because MedImmune Lacks Standing.

MedImmune also does not satisfy the "actual injury" test for Article III standing. Of course, the ripeness defects discussed above are dispositive, whether or not MedImmune had standing. Justiciability requires "not only the standing of litigants to assert particular claims, but also the appropriate timing of judicial intervention." *Renne v. Geary*, 501 U.S. 312, 320 (1991); *accord DaimlerChrysler*, 126 S. Ct. at 1867 ("The doctrines of mootness, ripeness, and political question all originate in Article III's 'case' or 'controversy' language, no less than standing does"). Thus, a dispute may be dismissed as unripe even when a plaintiff has standing.

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[17] For example, despite his broad view of declaratory relief, Professor Borchard emphasized that "in a suit by the alleged infringer of a patent against the patentee for a declaration that the petitioner is not infringing or that the defendant's patent is invalid, *a threat or claim of infringement emanating from the patentee* to the petitioner or his customers is *always necessary*" in order to "refute[] the fear that patentees might be harassed by prospective infringers and be obliged continually to defend their patents." Borchard, *Declaratory Judgments* at 43, 807 (emphasis added).

Compare Renne, 501 U.S. at 319-20 (finding standing), *with id.* at 320-23 (dismissing for lack of ripeness).

MedImmune lacks standing because it has not "suffered an 'injury in fact,'" or "the invasion of a legally protected interest" with a proximate "causal connection" to the conduct of Respondents. *Lujan*, 504 U.S. at 560. Although standing does not depend on the merits, "it often turns on the nature and source of the claim asserted." *Warth v. Seldin*, 422 U.S. 490, 500 (1975). The absence of Article III injury here is in part related to the point, discussed above, that in the Patent Act Congress gave substantive rights to patentees, not licensees or other hypothetical infringers. *See supra* at 26-28. Thus, MedImmune's claim of injury is "not to a legally cognizable right." *McConnell*, 540 U.S. at 227.

Indeed, far from being "injured" by Respondents, MedImmune has the unilateral power to decide whether to repudiate its license and stop paying royalties. *Infra* at 33-49. MedImmune has not done so because it wants to retain the license as a shield against suit – something Respondents are powerless to prevent. As Genentech explains at greater length in its brief, that kind of voluntary "personal choice" by the plaintiff cannot constitute an injury proximately caused by the defendant. *McConnell*, 540 U.S. at 228.

Nor can MedImmune satisfy the injury in fact requirement by arguing that it *might* be held liable for infringement *if* it repudiated the license. Even assuming that being held liable for committing a wrong against another private party could ever count as an injury to a legally protected interest – which seems dubious – any such possibility is entirely contingent and remote here. Since MedImmune will not repudiate its license, there is no "injury" of this kind. *Lujan*, 504 U.S. at 560 (injury must be actual or imminent, not conjectural or hypothetical).

II. Even Assuming Article III Allowed this Suit, Dismissal Should Be Affirmed on Prudential Grounds.

A. Jurisdiction Under the DJA Is Subject to Prudential and Equitable Limitations.

Even aside from the absence of an Article III controversy, prudential and equitable considerations bar the exercise of jurisdiction here. Like the other doctrines that cluster around "case or controversy," ripeness has a prudential dimension. *Reno v. Catholic Soc. Servs., Inc.*, 509 U.S. 43, 57 & n.18 (1993); *Renne*, 501 U.S. at 325 (Stevens, J., concurring). In addition to the bedrock requirements of Article III, courts must "evaluate . . . the hardship to the parties of withholding court consideration" before finding a case ripe. *Texas*, 523 U.S. at 301 (quotation marks omitted).

Prudential considerations apply with especial force to declaratory claims, where jurisdiction is inherently discretionary. 28 U.S.C. § 2201 (court "may" hear claim for declaratory relief). "The Declaratory Judgment Act was an authorization, not a command. It gave the federal courts competence to make a declaration of rights; it did not impose a duty to do so." *Public Affairs Assocs., Inc. v. Rickover*, 369 U.S. 111, 112 (1962). Thus, courts "possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995).

Exercises of that discretion must be guided by principles of equity:

> Congress . . . explicitly contemplated that the courts would decide to grant or withhold declaratory relief on the basis of traditional equitable principles. . . . [I]n an action for a declaratory judgment, the district

> court [is] as free as in any other suit in equity to grant or withhold the relief prayed, upon equitable grounds.

Samuels v. Mackell, 401 U.S. 66, 70 (1971) (quotation marks omitted); *accord Abbott Labs. v. Gardner*, 387 U.S. 136, 155 (1967); *Rickover*, 369 U.S. at 112. And when equity bars the suit, the proper response is for the court to decline to exercise jurisdiction at the outset. *Wilton*, 515 U.S. at 287-88. Indeed, the discretionary aspect of the DJA is tied to ripeness requirements for subject matter jurisdiction. *Catholic Soc. Servs.*, 509 U.S. at 57-58; *Abbott Labs.*, 387 U.S. at 148-49.

Categorical rules may govern the courts' equitable discretion to decline DJA jurisdiction in appropriate cases. *See Martin v. Franklin Capital Corp.*, 126 S. Ct. 704, 710 (2005) ("limiting discretion according to legal standards helps promote the basic principle of justice that like cases should be decided alike"); *Rickover*, 369 U.S. at 112. While equity sometimes requires fact-specific balancing of multiple factors by the trial court, reviewed for abuse of discretion, *e.g.*, *eBay, Inc. v. MercExchange, L.L.C.*, 126 S. Ct. 1837, 1839 (2006); *Wilton*, 515 U.S. at 282-83, 288-89, a rule of equity may govern an entire category of cases when a single consideration is decisive and no balancing is required. *See Wilton*, 515 U.S. at 289 (referring to "the exercise of 'judicial discretion, hardened by experience into rule'") (quoting Borchard, at 293). Such categorical rules govern declaratory jurisdiction in many cases. *E.g.*, *Samuels*, 401 U.S. at 68-73 (*Younger* abstention, which sounds in equity, applies to declaratory actions); *Cardinal*, 508 U.S. at 102-03.

B. Equity Bars a Licensee from Simultaneously Challenging a Patent's Validity and Keeping the Benefits of Its License for that Patent.

Under the long-standing rule of equity known as licensee estoppel, MedImmune cannot challenge the validity or enforceability of Cabilly II as long as it seeks to retain the

benefits of its license for that patent. A licensee in good standing shares in the property rights granted by the patent, because the licensee receives the right to use the invention without being threatened with infringement liability and benefits from the patent's exclusion of others from doing the same. *E.g.*, *Lear*, 395 U.S. at 669 & n.16. It would be inequitable under any circumstances to allow a licensee to continue laying claim to those rights and at the same time attack the patent that underlies them. But the inequity is especially great where, as here, the licensee seeks to preserve its favorable royalty rate at the same time it sues, so that it can keep the benefits of the license if it loses its lawsuit but escape its contractual obligation to pay royalties if it wins.

1. Under Traditional Equity Principles, a Licensee Must Repudiate the License Before Challenging the Underlying Patent.

Licensee estoppel has ancient roots and is derived from the even more venerable doctrine of lessee estoppel. *E.g.*, *Hayne v. Maltby*, 100 Eng. Rep. 665, 666-67 (K.B. 1789); *Taylor v. Hare*, 127 Eng. Rep. 461, 462 (C.P. 1805); *Cutler v. Bower*, 116 Eng. Rep. 736, 741 (K.B. 1848). *See generally* William C. Rooklidge, *Licensee Validity Challenges and the Obligation to Pay Accrued Royalties* (Part I), 68 J. Pat. & Trademark Off. Soc'y 506 (1986); *id.* (Part II), 69 J. Pat. & Trademark Off. Soc'y 5 (1987). In the first American licensee estoppel case, the court relied on the analogy to landlord-tenant law and explained that the estoppel equitably arises from the licensee's enjoyment of the fruits of the licensed property. *Wilder v. Adams*, 29 F. Cas. 1216, 1217-18 (C.C.D. Mass. 1846). Less than a decade later, this Court adopted the rule on the same grounds. *Kinsman v. Parkhurst*, 59 U.S. 289, 292-93 (1855); *see Lear*, 395 U.S. at 663 (recognizing that *Kinsman* "invoked estoppel in a considered manner").

Licensee estoppel is a rule of equity, not contract. It bars the licensee from attacking the patentee's title only as long as the licensee seeks to continue benefiting from the patent through the license – regardless what the license contract provides. Thus, even if a license prohibits the licensee from challenging patent validity or terminating the license as a matter of contract law, the rule of equity allows the licensee who believes that the patent is invalid to escape its contract obligations by *repudiating* the license and asserting invalidity in subsequent litigation. *See* Rooklidge (Part I), 68 J. Pat. & Trademark Off. Soc'y at 515-16, 519-22. Licensee estoppel is therefore more liberal to the licensee than ordinary contract rules, which do not allow a party to escape its bargain by repudiation.

In *St. Paul Plow-Works v. Starling*, 140 U.S. 184 (1891), for example, the licensee gave notice that it "renounced its license and all claim of right to construct plows in accordance with the plaintiff's patent." *Id.* at 186. The Court held that this repudiation did *not* terminate the license under contract law. *Id.* at 195. Nonetheless, having surrendered the benefits of the license, the repudiating licensee was not estopped from contesting the patent's validity as a defense. *Id.* at 196-98. In contrast, the United States as licensee was estopped from raising an invalidity defense in *United States v. Harvey Steel Co.*, 196 U.S. 310, 316 (1905), because the licensee "did not rescind the contract or give a notice which would have put the claimant on its guard, or enabled it to proceed against the manufacturers, but stood silent until the work was done and [the licensee] had received the fruits of [its] agreement." *Harvey Steel Co. v. United States*, 38 Ct. Cl. 662, 685 (1903), *aff'd*, 196 U.S. 310 (1905). Thus, as one oft-cited case explained, a licensee is estopped from denying the validity of the patent

> unless, prior to the period for which the royalties are sought to be recovered, he has given to the licensor a

> distinct, definite, and unequivocal notice to the effect that he no longer recognizes the binding force of the agreement, and that he will thereafter manufacture or use the article covered by the patent under a claim of right, founded upon the alleged invalidity of the patent, and in hostility to and defiance of the authority of the patent and the license, so that the licensor can thereafter proceed against him for an infringement of the patent, if he chooses to do so.

Martin v. New Trinidad Lake Asphalt Co., 255 F. 93, 94 (D.N.J. 1919).[18]

This "repudiation limitation place[s] both parties to the license agreement in an equitable position." Rooklidge (Part II), 69 J. Pat. & Trademark Off. Soc'y at 9. It bars the licensee "from challenging validity as long as he accept[s] the benefits of the license" but not "[o]nce the licensee repudiate[s] the license," because then "he not only g[ives] up any exclusive or deterrent effect, but also expose[s] himself to an infringement suit." Rooklidge (Part I), 68 J. Pat. & Trademark Off. Soc'y at 522.

2. *Lear* Was a Repudiation Case, and Its Holding Is Consistent with the Historical Equity Rule.

In the mid-20th century, however, a few cases held that licensee estoppel continued even after repudiation, and that misconception crept into this Court's opinions. In *Automatic Radio Manufacturing Co. v. Hazeltine Research, Inc.*, 176 F.2d 799 (1st Cir. 1949), *aff'd*, 339 U.S. 827 (1950), the lower court held that estoppel continued until the license itself was terminated according to its terms under contract law, regardless of repudiation by the licensee. 176 F.2d at

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[18] Similarly, even if a license has not been terminated under contract law, the licensee may challenge the patent if he has been "evicted" by a final court decision in favor of a third party holding that the patent is invalid. *See* Rooklidge (Part I), 68 J. Pat. & Trademark Off. Soc'y at 513-15.

809-10. Affirming, this Court stated the "general rule . . . that the licensee under a patent license agreement may not challenge the validity of the licensed patent," without noting that estoppel ends with repudiation. *Automatic Radio Mfg. Co. v. Hazeltine Research, Inc.*, 339 U.S. 827, 836 (1950).

Lear reflected *Hazeltine*'s confusion. The licensee in *Lear* became convinced that the licensed patent application was fully anticipated and invalid and so gave notice to the patentee and stopped paying royalties. 395 U.S. at 659-60. When the patentee sued for breach of license, the licensee argued – consistent with the traditional rule of equity – that "a licensee may escape the impact of estoppel simply by announcing that it has repudiated the licensing agreement, regardless of the contract's terms." *Id.* at 662 n.10. But the California Supreme Court held that the estoppel still applied, because the license "had not been validly terminated" under contract law. *Adkins v. Lear, Inc.*, 435 P.2d 321, 331 (Cal. 1967), *rev'd*, 395 U.S. 653 (1969).

That abandonment of the traditional scope of licensee estoppel truly "muzzled" the licensee as a potential challenger of the suspect patent's validity. *Lear*, 395 U.S. at 670. If (as in *Lear*) the license itself prohibited termination, then it could *permanently* estop the licensee from attacking the patent until it expired. That might be a reasonable rule of contract law, but it is not the traditional rule of equity that allows the licensee to escape its license obligations by repudiating its license benefits.

Thus, this Court's ruling in *Lear* allowing the repudiating licensee to assert patent invalidity as a defense was entirely consistent with the traditional scope of licensee estoppel. The *Lear* Court did not perceive that consistency, however, because it assumed that licensee estoppel always had the broader scope granted in *Hazeltine* and in the lower court ruling in *Lear* itself. *See* 395 U.S. at 668. *Lear* even viewed cases in which the estoppel did not apply due to repudiation

or eviction as exceptions that undermined licensee estoppel, not reflections of its equitable scope. *Id.* at 667-68. Thus, the "general rule" of *Hazeltine* that *Lear* rejected, *id.* at 671, was not licensee estoppel in its historical equitable form.[19]

In the first decade after *Lear*, lower courts divided over how far its rationale extended. The Sixth Circuit, for example, reaffirmed the traditional rule of equity: a licensee may not raise an invalidity defense until it repudiates the license by stopping royalty payments and giving notice that it is challenging the patent's validity. *PPG Indus., Inc. v. Westwood Chem., Inc.*, 530 F.2d 700, 706 (6th Cir. 1976); *see also id.* at 707 (holding however that *termination* of license is not required to challenge validity). In sharp contrast, the Second Circuit upheld a validity challenge by a licensee while allowing the licensee to keep the benefit of the license. *Warner-Jenkinson Corp. v. Allied Chem. Corp.*, 567 F.2d 184 (2d Cir. 1977). But apart from *Warner-Jenkinson*, there appears to be no clear-cut precedent for an offensive suit by a licensee in the position of MedImmune here.[20]

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[19] *Lear* also misread several cases it relied on. For example, it described *Pope Manufacturing Co. v. Gormully*, 144 U.S. 224 (1892), as an early case rejecting licensee estoppel, *Lear*, 395 U.S. at 663-64 – a mischaracterization echoed by MedImmune, Pet'r Br. 34. In fact, *Pope* was a case of extreme overreaching involving a "unique . . . contract" imposing "unusual and oppressive" obligations, which purported to bar the licensee from challenging the validity of *unlicensed* patents even *after the license terminated*. 144 U.S. at 232-33, 237. Licensee estoppel as a rule of equity never would have applied on those facts.

[20] For example, MedImmune and the United States incorrectly cite *American Sterilizer Co. v. Sybron Corp.*, 526 F.2d 542 (3d Cir. 1975), as precedent for this suit; but in that case the licensee actually "refused to pay any royalties, thereby giving rise to th[e] action" and exposing itself to counterclaims asserted by the patentee. *Id.* at 544. The one other case MedImmune and the United States cite as precedent, *Precision Shooting Equipment Co. v. Allen*, 646 F.2d 313 (7th Cir. 1981), arguably provides more support for their position, but even there the licensee appears to have breached the license by stopping royalty payments *before* bringing

Even this modest confusion ended in 1982, when Congress consolidated all patent appeals in the Federal Circuit to "increase doctrinal stability in the field of patent law" and thereby spur innovation by giving greater certainty to patent rights. S. Rep. No. 97-275, at 5-6 (1981), *reprinted in* 1982 U.S.C.C.A.N. 11, at 15-16. From the outset, the Federal Circuit has indicated that the historical requirement of repudiation remains a precondition for validity challenges by licensees. *See* Rooklidge (Part II), 69 J. Pat. & Trademark Off. Soc'y at 19-21. And the Federal Circuit unequivocally reaffirmed that rule almost a decade ago – before the license between Genentech and MedImmune was entered into – by holding that licensee estoppel continues to apply until the licensee "(i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid." *Studiengesellschaft*, 112 F.3d at 1568.

Thus, with at most one or two scattered exceptions a quarter century ago, suits attacking patents by licensees in good standing have *never* been allowed in our judicial system – and certainly never by this Court. While MedImmune would have the Court believe that the Federal Circuit's decision in *Gen-Probe* was a radical departure from existing law, just the opposite is true: it is MedImmune's license-and-sue strategy that is essentially unprecedented.

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suit. *See Precision Shooting Equip. Inc. v. Holless W. Allen Inc.*, 492 F. Supp. 79, 86-87 (C.D. Ill. 1980), *aff'd*, 646 F.2d 313 (7th Cir. 1981). Admittedly, not all of the cases are clear. Much of the confusion – which MedImmune exploits – stems from the courts' post-*Lear* use of "repudiation" and "termination" interchangeably. *E.g.*, *PPG*, 530 F.2d at 707. Based on that purely semantic imprecision, *Warner-Jenkinson* even cited *PPG* as support for the novel holding that "repudiation of the licensing agreement should not be precondition to suit," 567 F.2d at 187, when in fact *PPG* held that breach plus notice to the patentee – repudiation in substance – was required, 530 F.2d at 706.

C. Suits Like This Conflict with Fundamental Patent Policies.

1. Retaining Repudiation as a Precondition of Suit Furthers the Core Purposes of Patent Law.

The question is thus whether the Court will upset settled understandings to allow licensees like MedImmune to lock in favorable license terms and sue at the same time, so that the licensee can keep the benefits of the license contract if it loses the lawsuit but escape its contractual obligation to pay royalties if it wins. Such "a major departure from the long tradition of equity practice should not be lightly" undertaken. *eBay*, 126 S. Ct. at 1839 (quotation marks omitted).

MedImmune (and the United States) argue that despite the unfairness of MedImmune's strategy, it should be allowed in furtherance of the "patent policy" of eliminating invalid patents. That blinkered approach fails even to acknowledge the fundamental purpose of patent law: to "promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries." U.S. Const. art. I, § 8, cl. 8; *see also, e.g.*, *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). Nor does it mention the strong public interest in the efficient exploitation of technology through licensing arrangements, which "increase the value of intellectual property to consumers and to the developers of the technology." U.S. Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* 5 (1995) ("*DOJ/FTC Licensing Guidelines*"). While the interest in eliminating invalid patents is not insubstantial, it must be balanced against these competing and fundamental purposes of patent law. *E.g., Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 221 (1980) (rejecting argument that policy of free competition

trumps "the policy of stimulating invention that underlies the entire patent system").

It is true that *Lear* itself failed even to mention the importance of incentives for invention and disclosure provided by our patent and licensing system, and instead treated elimination of invalid patents as the sole policy to be considered. But that one-sidedness was a defect in *Lear* that later decisions like *Dawson* and *Bonito Boats* rejected. *Lear* stands near the high-water mark of judicial suspicion of patents and patent licensing, which was also manifested in the Court's creation of expansive patent misuse doctrines based on antitrust concepts that have since been discredited – but that *Lear* relied on. 395 U.S. at 663, 666-67. After *Lear*, Congress rolled back the extravagant patent misuse theories of that era. 35 U.S.C. § 271(d) (providing that various licensing practices are not patent misuse in absence of market power); *see also Dawson*, 448 U.S. at 213; *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 126 S. Ct. 1281, 1290 (2006).

Rules that promote efficient licensing for technology transfer are critical for furthering fundamental patent goals. As the United States acknowledges, "patent licensing in general should be encouraged because it allows the efficient exploitation of technology and promotes competition and innovation." U.S. Br. 23-24; *see id.* at 2 ("intellectual property licensing can enhance consumer welfare by allowing for the efficient exploitation of intellectual property"); *DOJ/FTC Licensing Guidelines*, at 5 (licensing "can lead to more efficient exploitation of the intellectual property, benefiting consumers through the reduction of costs and the introduction of new products"). This Court, too, recently observed with approval that "some patent holders, such as university researchers or self-made inventors, might reasonably prefer to license their patents, rather than undertake efforts to secure the financing necessary to bring their works to market themselves." *eBay*, 126 S. Ct. at 1840.

Congress has strongly endorsed patent licensing. In addition to legislatively overruling decisions from the *Lear* era that proscribed licensing practices as patent misuse, 35 U.S.C. § 271(d)(1), (2), (4), in 1980 Congress enacted the Bayh-Dole Act, 35 U.S.C. § 200 *et seq.*, to allow nonprofit organizations that receive federal research funds (like City of Hope) to obtain title to patents resulting from such research and to license them for commercial exploitation. Bayh-Dole declared it a "policy and objective of the Congress" to promote such licensing. *Id.* § 200. The ability to enter into efficient licensing relationships not only ensures that new technology is put to its highest and best use, but also substantially augments the incentive to engage in the research that leads to new technologies in the first place – the very *raison d'etre* of the patent system. Not surprisingly, the pro-licensing regime of the Bayh-Dole Act has led to a wide array of life-saving and life-enhancing products, including vaccines, cancer therapies, and glaucoma treatments. Council on Governmental Relations, *The Bayh-Dole Act: A Guide to the Law and Implementing Regulations* (1999), *available at* http://www.ucop.edu/ott/faculty/bayh.html.

MedImmune's rule would undermine these core patent objectives by creating perverse incentives for inefficient licensing or no licensing at all. The price of a license necessarily reflects a compromise based on the parties' assessment of the likely cost and outcome of an infringement suit that the license precludes, including whether defenses such as invalidity and unenforceability would be upheld and, when an *application* is being licensed, the likelihood that any patent will issue at all. Thus, "the more likely that a patent will be found invalid if litigated, the lower the royalties it can command in licensing negotiations. After all, licensing takes place in the shadow of litigation, with licensing rates determined by the relative bargaining power of the patent holder and potential licensees/alleged infringers." Carl

Shapiro, *Patent System Reform: Economic Analysis and Critique*, 19 Berkeley Tech. L.J. 1017, 1034 (2004); *see also, e.g.*, 1 Jay Dratler, Jr., *Licensing of Intellectual Property* § 4.02[3][b] (2006) (factor in setting royalty is "likelihood that the patent will be held valid if challenged in court").

On MedImmune's theory, however, the license would lock only the patentee into the compromise price. The licensee could, at any time, try to escape its obligation under the license to pay the compromise royalty by attacking the patent's validity, even as it maintains the protection of the license in the event its lawsuit fails. The license would also reverse the remedial scheme created by Congress by giving the licensee complete and unfettered control over the timing and venue for litigation while tying the patentee's hands. The license would protect only the licensee, not the patentee. The Federal Circuit rightly stressed "the inequity" of MedImmune's proposed rule "when the patent owner, having contracted away its right to sue, is in continuing risk of attack on the patent whenever and wherever the licensee chooses – for example, if the product achieves commercial success – while the licensee can preserve its license and royalty rate if the attack fails." Pet. App. 7a.

Under such a regime, patentees will be much more reluctant to enter into licenses with compromise royalty rates than they are now. Some patentees will forgo licensing altogether to preserve their right to bring infringement suits. After all, the downside risk to the patentee of suing for infringement would be exactly the same as the downside of entering into a license under MedImmune's proposal: "extremely expensive," "lengthy," and "disruptive patent litigation." U.S. Br. 26. But the upside to the patentee of preserving the right to sue for infringement would be much greater than under a license, because the patentee could seek the statutory relief provided by Congress for infringement (rather than the compromise royalty rate) and would also

retain significant control over the time and place of litigation. The result would be increased incentives to choose costly litigation over contractual compromise – since the compromise does not preclude the litigation anyway.

In other instances, patentees might still enter into licenses, but would demand a higher royalty rate to cover their increased risks. The United States admits as much by proposing that patentees could "require prospective licensees to purchase a fully paid-up license" to overcome their risk under MedImmune's proposal. U.S. Br. 29; *see also* Paul A. Ragusa & Samantha M. French, *To Pay or Not To Pay*, 7 Patent Strategy & Management 1, 8 (2006) (under MedImmune's proposed rule, patentees "may consider demanding security, e.g., in the form of an initial lump-sum payment, as a hedge to cover future uncertainty").[21] That simply confirms that the MedImmune rule would raise royalty rates and, ultimately, prices for consumers. Moreover, the United States' proposal of fully paid licenses is economically unrealistic in many industries, including biotechnology, where potential infringers seek the protection of a license before *beginning* costly development of "pipeline" products that may never be approved for marketing, much less achieve commercial success. *See* Pharm. Research & Mfrs. of Am., *Pharmaceutical Industry Profile 2005*, at 4-5 (2005) (describing drug development process), *available at* http://www.phrma.org/files/2005 IndustryReport.pdf. As a result, the prohibitive cost of a

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[21] The United States suggests that higher royalties would be necessary only when "a would-be licensee . . . makes clear that it disputes the validity or applicability of the patent." U.S. Br. 28. But that is obviously false. Licensees could always adopt the very strategy chosen by MedImmune here: conceal the intent to sue until after the favorable royalty rate is negotiated and the license is signed. Every patentee would potentially face that risk from every licensee and would demand higher royalties to offset it.

fully paid-up license would frequently cause prospective licensees to abandon programs using patented technology for developing important new products before they get off the ground. When it sought additional licenses for its "pipeline" products, MedImmune itself stressed that "Genentech's licensing policy with respect to the [Cabilly II] patent has the potential to be a significant factor in MedImmune's research and development strategies." J.A. 431. Thus, as the United States previously explained to the Court, "a rule of law effectively requiring payments in a lump sum . . . would reduce the incentive to invent." Br. for United States as Amicus Curiae, *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257 (1978) (No. 77-1413), 1978 WL 207171, at *23.

Nor is there merit to the United States' blithe assertion that this serious disruption to innovation and technology transfer would affect only a subset of suspect patents. U.S. Br. 26 ("Many patents are clearly valid, and thus are unlikely to be challenged"). As every patent lawyer knows, a well-heeled litigant can amass prior art references or concoct other bases to challenge the validity of virtually *any* patent. With no downside risk to the licensee if it loses, such challenges will almost always be worth pursuing, regardless of merit, once "the product achieves commercial success," Pet. App. 7a, and the resulting royalties become substantial – exactly the situation here. Indeed, a commercial venture with enormous revenues like MedImmune may use a costly validity strike suit to bully nonprofit research institutions like City of Hope into one-sided settlements regardless of the suit's merit. *See* 126 Cong. Rec. 29890, 29896 (1980) (statement of Rep. Smith) ("Evidence shows that the high cost of defending a patent is sometimes used to blackmail the owner into permitting infringements or into selling out at greatly reduced price").

These distortions are not needed to "unmuzzle" licensees to challenge suspect patents. *Lear* and the traditional

licensee estoppel rule ensure that licensees are always free to repudiate their license obligations in order to challenge validity. The situation here is completely different from the posture of *Lear* coming out of the California Supreme Court, which ruled that a license contract could permanently bar a validity suit by prohibiting termination. *Supra* at 37. MedImmune is free at any time to launch its attack – if it repudiates first.[22] To be sure, by shifting some risk to the licensee, the precondition of repudiation might sometimes lead licensees not to file validity suits. But as just discussed, maintaining some downside risk for licensees is a salutary measure for preventing meritless strike suits in this posture. There is no reason why a license should impose all the risk of litigation on patentees, and none on licensees.

Moreover, under legislation enacted after *Lear*, any person can initiate an administrative reexamination proceeding ubject to substantive limitations imposed by Congress.[23] Congress created this new "system of administrative reexamination of patents" to "strengthen[] investor confidence in the certainty of patent rights," which Congress believed were undermined by the cost, duration, and uncertainty of patent validity litigation in court. H.R. Rep. No. 96-1307, Part I, at 3-4 (1980). MedImmune not

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[22] In addition, the license agreement here allows MedImmune to terminate at will without breach on six months' notice. J.A. 409 § 7.04.

[23] The most important limitation is that both *ex parte* and *inter partes* reexamination may only be based on "prior art consisting of patents or printed publications," not other grounds for contesting patentability. 35 U.S.C. § 301; *see id.* §§ 302, 311(a). An *ex parte* requester also does not have a right to judicial review of a decision upholding the patent. *Id.* § 306. And although an *inter partes* requester may seek judicial review (assuming Article III is satisfied), *id.* § 315(b), Congress declined to extend *inter partes* procedures to preexisting patents like Cabilly II. *See* Pub. L. No. 106-113, tit. IV, § 4608(a), 113 Stat. 1501, 1536, 1501A-572 (1999).

only can use this administrative procedure – it has done so. Pet'r. Br. 48 n.18.

MedImmune's right to repudiate (or terminate on six months' notice) also gives the lie to its suggestion that its rule is needed to allow licensees to escape from bad bargains when circumstances change after a license is signed.[24] MedImmune's conduct belies any notion that unforeseen developments have made the license undesirable to it. Just the opposite is true: MedImmune's entire strategy is to avoid repudiation so it can *keep* the license. *Lear* and the traditional rule of equity already give MedImmune the right to escape from the bargain it made by repudiating and then attacking the validity of Cabilly II. Alleged changed circumstances cannot justify the one-sided rule sought by MedImmune.[25]

2. The Serious Flaws in MedImmune's Proposal Cannot Be Eliminated by Contract Rules.

The United States effectively acknowledges that patent policy does not really favor MedImmune's rule, *i.e.*, does not "entitle a licensee both to challenge the licensed patent and to retain all the benefits of his license agreement." U.S. Br. 28. But the United States contends that the licensee should have

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[24] As a factual matter, there is no merit to MedImmune's repeated complaints that the issuance of the Cabilly II Patent was somehow unforeseen. The possibility that Genentech and City of Hope would receive such a patent was expressly contemplated by the parties when they included the Cabilly II Application in the license, precisely so that MedImmune could not be sued for infringement if Respondents prevailed in the interference and received the patent. *Supra* at 5.

[25] Similarly, that several related patents are covered by the license does not favor allowing a validity challenge to one of the patents without repudiation. MedImmune chose for its own convenience to license multiple patents as a comprehensive shield against infringement suits. J.A. 402. Moreover, when parties license multiple patents, repudiation as to one would not necessarily trigger termination of the license as to others.

its cake and eat it too unless "the agreement expressly provides otherwise." *Id.* That importation of contract principles here is neither logical nor realistic. If patent policy truly favored the MedImmune rule, the United States would not try to reassure the Court that parties can avoid it contractually (nor conspicuously assert that the Government's own patents would be exempt from the rule it espouses, U.S. Br. 23 n.11). Indeed, if patentees could contract around the rule, in the future they would insist on express license terms providing that an attack on the patent's validity is a material breach of the license, *i.e.*, a repudiation. That would merely return future generations of licenses to the historical estoppel rule that has always applied.

In the meantime, the United States' proposal would unleash massive uncertainty about licenses negotiated before the announcement of this new rule. The scope of licensee estoppel has never been determined by contract. *Supra* at 34-39; *Lear*, 395 U.S. at 673 ("The parties' contract . . . is no[t] controlling on this issue"). The United States' rule would thus spawn a wave of satellite litigation about whether the current generation of patent licenses expressly or impliedly provide that filing litigation like this is a material breach – a topic the parties never contemplated as a matter for negotiation – and whether such a provision is enforceable. *See* U.S. Br. 28 ("the enforceability of such provisions is an open question"). As the brief of *amicus* Licensing Executive Society in support of neither party emphasizes, both licensors and licensees need additional certainty here, not the pervasive uncertainty that would be caused by this new rule.

In any event, if the license terms were controlling, they would bar this suit. The license here provides that MedImmune must pay royalties so long as the patents "have neither expired nor been held invalid by a court or other body of competent jurisdiction from which no appeal has been or may be taken." J.A. 399. As this Court explained a century

ago in construing a nearly identical provision – a "wellknown and conventional one in licenses" – such "proviso[s] [are] inserted . . . on the assumption that a licensee . . . *is estopped to deny the validity of the patent* which he has been using, and to give him the benefit of litigation by or against third persons, notwithstanding that rule." *Harvey*, 196 U.S. at 317 (emphasis added). Hence, "[i]t would not be enough to say that the [licensee] thought the patent bad, and would like to have the court decide so now." *Id.* at 316. MedImmune's contractual obligation is thus to pay royalties until the patent expires or is invalidated by a final decision in third-party litigation. This is a suit to *evade* that contractual obligation. And *Studiengesellschaft* provides the background rule implicitly incorporated into the parties' understanding: MedImmune cannot attack the patent in order to evade its contractual obligations unless it first repudiates the contract.

D. As a Matter of Constitutional Avoidance, the Court Should Affirm on These Prudential Grounds.

The Court can and should affirm on these prudential grounds. In the courts below, City of Hope and Genentech properly relied on binding Circuit precedent deciding the jurisdictional issue under Article III, and so had no occasion to press the argument that prudential considerations also bar the exercise of jurisdiction. But because the issue is jurisdictional – albeit prudential and discretionary – this Court may address it in the first instance, with or without deciding the Article III question. *Catholic Soc. Servs.*, 509 U.S. at 57 n.18 ("Even when a ripeness question in a particular case is prudential, we may raise it on our own motion, and cannot be bound by the wishes of the parties") (quotation marks omitted); *Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 11-18 & n.8 (2004); *Steel Co.*, 523 U.S. at 100 n.3; *id.* at 115 (opinion of Stevens, J.). Indeed, in *Cardinal*, even after finding Article III satisfied, the Court

sua sponte decided a discretionary jurisdiction question that had not been addressed by the Federal Circuit or briefed by the parties. *See* 508 U.S. at 103-04 (opinion of Scalia, J.).

MedImmune itself has consistently argued that the scope of licensee estoppel after *Lear* is directly relevant to the question of jurisdiction. *E.g.*, Pet. App. 4a-5a; Pet'r Br. 34-38. MedImmune and the United States have also both briefed issues of "patent policy" relevant to the prudential jurisdiction question, not Article III. Pet'r Br. 38-50; U.S. Br. 23-30. The Federal Circuit, too, has made its views known. It has unequivocally stated that the judgment on review is compelled by equity. Pet. App. 7a; *Gen-Probe*, 359 F.3d at 1382. And its cases culminating in *Studiengesellschaft* unambiguously demonstrate its reaffirmation of the historical scope of licensee estoppel.

Most importantly, affirmance on this basis is favored by the doctrine of constitutional avoidance – "the deeply rooted commitment not to pass on questions of constitutionality unless adjudication of the constitutional issue is necessary." *Newdow*, 542 U.S. at 11 (quotation marks omitted). As set forth above, this Court has never held that there is a justiciable controversy supporting a DJA suit where, as here, neither party could sue for a traditional coercive remedy. The Court should not sail into those uncharted waters now, when MedImmune's suit is jurisdictionally barred by equity in any event.

CONCLUSION

The judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

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STATUTORY ADDENDUM

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U.S. Const. art. I, § 8, cl. 8

The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

U.S. Const. art. III, § 2, cl. 1

The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority;—to all Cases affecting Ambassadors, other public Ministers and Consuls;—to all Cases of admiralty and maritime Jurisdiction;—to Controversies to which the United States shall be a Party;—to Controversies between two or more States;—between a State and Citizens of another State;—between Citizens of different States;—between Citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.

28 U.S.C. § 2201. Creation of remedy

(a) In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1986, a proceeding under section 505 or 1146 of title 11, or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of merchandise of a free trade area country (as defined in section 516A(f)(10) of the Tariff Act of 1930), as determined by the administering authority, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested

party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

(b) For limitations on actions brought with respect to drug patents see section 505 or 512 of the Federal Food, Drug, and Cosmetic Act.

35 U.S.C. § 131. Examination of application

The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor.

35 U.S.C. § 134. Appeal to the Board of Patent Appeals and Interferences

(a) Patent applicant. An applicant for a patent, any of whose claims has been twice rejected, may appeal from the decision of the primary examiner to the Board of Patent Appeals and Interferences, having once paid the fee for such appeal.

(b) Patent owner. A patent owner in any reexamination proceeding may appeal from the final rejection of any claim by the primary examiner to the Board of Patent Appeals and Interferences, having once paid the fee for such appeal.

(c) Third-party. A third-party requester in an inter partes proceeding may appeal to the Board of Patent Appeals and Interferences from the final decision of the primary examiner favorable to the patentability of any original or proposed amended or new claim of a patent, having once paid the fee for such appeal.

35 U.S.C. § 135. Interferences

(a) Whenever an application is made for a patent which, in the opinion of the Director, would interfere with any pending application, or with any unexpired patent, an interference may be declared and the Director shall give notice of such declaration to the applicants, or applicant and patentee, as the case may be. The Board of Patent Appeals and Interferences shall determine questions of priority of the inventions and may determine questions of patentability. Any final decision, if adverse to the claim of an applicant, shall constitute the final refusal by the Patent and Trademark Office of the claims involved, and the Director may issue a patent to the applicant who is adjudged the prior inventor. A final judgment adverse to a patentee from which no appeal or other review has been or can be taken or had shall constitute cancellation of the claims involved in the patent, and notice of such cancellation shall be endorsed on copies of the patent distributed after such cancellation by the Patent and Trademark Office.

(b)(1) A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

(2) A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an application published under section 122(b) of this title may be made in an application filed after the application is published only if the claim is made before 1 year after the date on which the application is published.

(c) Any agreement or understanding between parties to an interference, including any collateral agreements referred to

therein, made in connection with or in contemplation of the termination of the interference, shall be in writing and a true copy thereof filed in the Patent and Trademark Office before the termination of the interference as between the said parties to the agreement or understanding. If any party filing the same so requests, the copy shall be kept separate from the file of the interference, and made available only to Government agencies on written request, or to any person on a showing of good cause. Failure to file the copy of such agreement or understanding shall render permanently unenforceable such agreement or understanding and any patent of such parties involved in the interference or any patent subsequently issued on any application of such parties so involved. The Director may, however, on a showing of good cause for failure to file within the time prescribed, permit the filing of the agreement or understanding during the six-month period subsequent to the termination of the interference as between the parties to the agreement or understanding.

The Director shall give notice to the parties or their attorneys of record, a reasonable time prior to said termination, of the filing requirement of this section. If the Director gives such notice at a later time, irrespective of the right to file such agreement or understanding within the six-month period on a showing of good cause, the parties may file such agreement or understanding within sixty days of the receipt of such notice.

Any discretionary action of the Director under this subsection shall be reviewable under section 10 of the Administrative Procedure Act.

(d) Parties to a patent interference, within such time as may be specified by the Director by regulation, may determine such contest or any aspect thereof by arbitration. Such arbitration shall be governed by the provisions of title 9 to

the extent such title is not inconsistent with this section. The parties shall give notice of any arbitration award to the Director, and such award shall, as between the parties to the arbitration, be dispositive of the issues to which it relates. The arbitration award shall be unenforceable until such notice is given. Nothing in this subsection shall preclude the Director from determining patentability of the invention involved in the interference.

35 U.S.C. § 141. Appeal to Court of Appeals for the Federal Circuit

An applicant dissatisfied with the decision in an appeal to the Board of Patent Appeals and Interferences under section 134 of this title may appeal the decision to the United States Court of Appeals for the Federal Circuit. By filing such an appeal the applicant waives his or her right to proceed under section 145 of this title. A patent owner, or a third-party requester in an inter partes reexamination proceeding, who is in any reexamination proceeding dissatisfied with the final decision in an appeal to the Board of Patent Appeals and Interferences under section 134 may appeal the decision only to the United States Court of Appeals for the Federal Circuit. A party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference may appeal the decision to the United States Court of Appeals for the Federal Circuit, but such appeal shall be dismissed if any adverse party to such interference, within twenty days after the appellant has filed notice of appeal in accordance with section 142 of this title, files notice with the Director that the party elects to have all further proceedings conducted as provided in section 146 of this title. If the appellant does not, within thirty days after the filing of such notice by the adverse party, file a civil action under section 146, the decision appealed from shall govern the further proceedings in the case.

35 U.S.C. § 145. Civil action to obtain patent

An applicant dissatisfied with the decision of the Board of Patent Appeals and Interferences in an appeal under section 134(a) of this title may, unless appeal has been taken to the United States Court of Appeals for the Federal Circuit, have remedy by civil action against the Director in the United States District Court for the District of Columbia if commenced within such time after such decision, not less than sixty days, as the Director appoints. The court may adjudge that such applicant is entitled to receive a patent for his invention, as specified in any of his claims involved in the decision of the Board of Patent Appeals and Interferences, as the facts in the case may appear and such adjudication shall authorize the Director to issue such patent on compliance with the requirements of law. All the expenses of the proceedings shall be paid by the applicant.

35 U.S.C. § 146. Civil action in case of interference

Any party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference, may have remedy by civil action, if commenced within such time after such decision, not less than sixty days, as the Director appoints or as provided in section 141 of this title, unless he has appealed to the United States Court of Appeals for the Federal Circuit, and such appeal is pending or has been decided. In such suits the record in the Patent and Trademark Office shall be admitted on motion of either party upon the terms and conditions as to costs, expenses, and the further cross-examination of the witnesses as the court imposes, without prejudice to the right of the parties to take further testimony. The testimony and exhibits of the record in the Patent and Trademark Office when admitted shall have the same effect as if originally taken and produced in the suit.

Such suit may be instituted against the party in interest as shown by the records of the Patent and Trademark Office at the time of the decision complained of, but any party in interest may become a party to the action. If there be adverse parties residing in a plurality of districts not embraced within the same state, or an adverse party residing in a foreign country, the United States District Court for the District of Columbia shall have jurisdiction and may issue summons against the adverse parties directed to the marshal of any district in which any adverse party resides. Summons against adverse parties residing in foreign countries may be served by publication or otherwise as the court directs. The Director shall not be a necessary party but he shall be notified of the filing of the suit by the clerk of the court in which it is filed and shall have the right to intervene. Judgment of the court in favor of the right of an applicant to a patent shall authorize the Director to issue such patent on the filing in the Patent and Trademark Office of a certified copy of the judgment and on compliance with the requirements of law.

35 U.S.C. § 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the

same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date

which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under

section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a

patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

35 U.S.C. § 281. Remedy for infringement of patent

A patentee shall have remedy by civil action for infringement of his patent.

35 U.S.C. § 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section

103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

(1) Noninfringement, absence of liability for infringement or unenforceability,

(2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,

(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,

(4) Any other fact or act made a defense by this title.

In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires. Invalidity of the extension of a patent term or any portion thereof under

section 154(b) or 156 of this title because of the material failure—

(1) by the applicant for the extension, or

(2) by the Director,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.

35 U.S.C. § 283. Injunction

The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

35 U.S.C. § 284. Damages

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed. Increased damages under this paragraph shall not apply to provisional rights under section 154(d) of this title.

The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

35 U.S.C. § 285. Attorney fees

The court in exceptional cases may award reasonable attorney fees to the prevailing party.

35 U.S.C. § 301. Citation of prior art

Any person at any time may cite to the Office in writing prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent. If the person explains in writing the pertinency and manner of applying such prior art to at least one claim of the patent, the citation of such prior art and the explanation thereof will become a part of the official file of the patent. At the written request of the person citing the prior art, his or her identity will be excluded from the patent file and kept confidential.

35 U.S.C. § 302. Request for reexamination

Any person at any time may file a request for reexamination by the Office of any claim of a patent on the basis of any prior art cited under the provisions of section 301 of this title. The request must be in writing and must be accompanied by payment of a reexamination fee established by the Director pursuant to the provisions of section 41 of this title. The request must set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested. Unless the requesting person is the owner of the patent, the Director promptly will send a copy of the request to the owner of record of the patent.

35 U.S.C. § 303. Determination of issue by Director

(a) Within three months following the filing of a request for reexamination under the provisions of section 302 of this

title, the Director will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. On his own initiative, and any time, the Director may determine whether a substantial new question of patentability is raised by patents and publications discovered by him or cited under the provisions of section 301 of this title. The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.

(b) A record of the Director's determination under subsection (a) of this section will be placed in the official file of the patent, and a copy promptly will be given or mailed to the owner of record of the patent and to the person requesting reexamination, if any.

(c) A determination by the Director pursuant to subsection (a) of this section that no substantial new question of patentability has been raised will be final and nonappealable. Upon such a determination, the Director may refund a portion of the reexamination fee required under section 302 of this title.

35 U.S.C. § 304. Reexamination order by Director

If, in a determination made under the provisions of subsection 303(a) of this title, the Director finds that a substantial new question of patentability affecting any claim of a patent is raised, the determination will include an order for reexamination of the patent for resolution of the question. The patent owner will be given a reasonable period, not less than two months from the date a copy of the determination is given or mailed to him, within which he may file a statement on such question, including any amendment to his patent and

new claim or claims he may wish to propose, for consideration in the reexamination. If the patent owner files such a statement, he promptly will serve a copy of it on the person who has requested reexamination under the provisions of section 302 of this title. Within a period of two months from the date of service, that person may file and have considered in the reexamination a reply to any statement filed by the patent owner. That person promptly will serve on the patent owner a copy of any reply filed.

35 U.S.C. § 305. Conduct of reexamination proceedings

After the times for filing the statement and reply provided for by section 304 of this title have expired, reexamination will be conducted according to the procedures established for initial examination under the provisions of sections 132 and 133 of this title. In any reexamination proceeding under this chapter, the patent owner will be permitted to propose any amendment to his patent and a new claim or claims thereto, in order to distinguish the invention as claimed from the prior art cited under the provisions of section 301 of this title, or in response to a decision adverse to the patentability of a claim of a patent. No proposed amended or new claim enlarging the scope of a claim of the patent will be permitted in a reexamination proceeding under this chapter. All reexamination proceedings under this section, including any appeal to the Board of Patent Appeals and Interferences, will be conducted with special dispatch within the Office.

35 U.S.C. § 306. Appeal

The patent owner involved in a reexamination proceeding under this chapter may appeal under the provisions of section 134 of this title, and may seek court review under the provisions of sections 141 to 145 of this title, with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the patent.

35 U.S.C. § 307. Certificate of patentability, unpatentability, and claim cancellation

(a) In a reexamination proceeding under this chapter, when the time for appeal has expired or any appeal proceeding has terminated, the Director will issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent any proposed amended or new claim determined to be patentable.

(b) Any proposed amended or new claim determined to be patentable and incorporated into a patent following a reexamination proceeding will have the same effect as that specified in section 252 of this title for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation for the same, prior to issuance of a certificate under the provisions of subsection (a) of this section.

35 U.S.C. § 311. Request for inter partes reexamination

(a) In general.—Any third-party requester at any time may file a request for inter partes reexamination by the Office of a

patent on the basis of any prior art cited under the provisions of section 301.

(b) Requirements.—The request shall—

(1) be in writing, include the identity of the real party in interest, and be accompanied by payment of an inter partes reexamination fee established by the Director under section 41; and

(2) set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested.

(c) Copy.—The Director promptly shall send a copy of the request to the owner of record of the patent.

35 U.S.C. § 312. Determination of issue by Director

(a) Reexamination.—Not later than 3 months after the filing of a request for inter partes reexamination under section 311, the Director shall determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.

(b) Record.—A record of the Director's determination under subsection (a) shall be placed in the official file of the patent, and a copy shall be promptly given or mailed to the owner of record of the patent and to the third-party requester.

(c) Final decision.—A determination by the Director under subsection (a) shall be final and non-appealable. Upon a

determination that no substantial new question of patentability has been raised, the Director may refund a portion of the inter partes reexamination fee required under section 311.

35 U.S.C. § 313. Inter partes reexamination order by Director

If, in a determination made under section 312(a), the Director finds that a substantial new question of patentability affecting a claim of a patent is raised, the determination shall include an order for inter partes reexamination of the patent for resolution of the question. The order may be accompanied by the initial action of the Patent and Trademark Office on the merits of the inter partes reexamination conducted in accordance with section 314.

35 U.S.C. § 314. Conduct of inter partes reexamination proceedings

(a) In general.—Except as otherwise provided in this section, reexamination shall be conducted according to the procedures established for initial examination under the provisions of sections 132 and 133. In any inter partes reexamination proceeding under this chapter, the patent owner shall be permitted to propose any amendment to the patent and a new claim or claims, except that no proposed amended or new claim enlarging the scope of the claims of the patent shall be permitted.

(b) Response.—(1) With the exception of the inter partes reexamination request, any document filed by either the patent owner or the third-party requester shall be served on the other party. In addition, the Office shall send to the third-party requester a copy of any communication sent by the

Office to the patent owner concerning the patent subject to the inter partes reexamination proceeding.

(2) Each time that the patent owner files a response to an action on the merits from the Patent and Trademark Office, the third-party requester shall have one opportunity to file written comments addressing issues raised by the action of the Office or the patent owner's response thereto, if those written comments are received by the Office within 30 days after the date of service of the patent owner's response.

[(3) Redesignated (2)]

(c) Special dispatch.—Unless otherwise provided by the Director for good cause, all inter partes reexamination proceedings under this section, including any appeal to the Board of Patent Appeals and Interferences, shall be conducted with special dispatch within the Office.

35 U.S.C. § 315. Appeal

(a) Patent owner.—The patent owner involved in an inter partes reexamination proceeding under this chapter—

(1) may appeal under the provisions of section 134 and may appeal under the provisions of sections 141 through 144, with respect to any decision adverse to the patentability of any original or proposed amended or new claim of the patent; and

(2) may be a party to any appeal taken by a third-party requester under subsection (b).

(b) Third-party requester.—A third-party requester—

(1) may appeal under the provisions of section 134, and may appeal under the provisions of sections 141 through 144,

with respect to any final decision favorable to the patentability of any original or proposed amended or new claim of the patent; and

(2) may, subject to subsection (c), be a party to any appeal taken by the patent owner under the provisions of section 134 or sections 141 through 144.

(c) Civil action.—A third-party requester whose request for an inter partes reexamination results in an order under section 313 is estopped from asserting at a later time, in any civil action arising in whole or in part under section 1338 of title 28, the invalidity of any claim finally determined to be valid and patentable on any ground which the third-party requester raised or could have raised during the inter partes reexamination proceedings. This subsection does not prevent the assertion of invalidity based on newly discovered prior art unavailable to the third-party requester and the Patent and Trademark Office at the time of the inter partes reexamination proceedings.

35 U.S.C. § 316. Certificate of patentability, unpatentability, and claim cancellation

(a) In general.—In an inter partes reexamination proceeding under this chapter, when the time for appeal has expired or any appeal proceeding has terminated, the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent any proposed amended or new claim determined to be patentable.

(b) Amended or new claim.—Any proposed amended or new claim determined to be patentable and incorporated into a patent following an inter partes reexamination proceeding

shall have the same effect as that specified in section 252 of this title for reissued patents on the right of any person who made, purchased, or used within the United States, or imported into the United States, anything patented by such proposed amended or new claim, or who made substantial preparation therefor, prior to issuance of a certificate under the provisions of subsection (a) of this section.

35 U.S.C. § 317. Inter partes reexamination prohibited

(a) Order for reexamination.—Notwithstanding any provision of this chapter, once an order for inter partes reexamination of a patent has been issued under section 313, neither the third-party requester nor its privies, may file a subsequent request for inter partes reexamination of the patent until an inter partes reexamination certificate is issued and published under section 316, unless authorized by the Director.

(b) Final decision.—Once a final decision has been entered against a party in a civil action arising in whole or in part under section 1338 of title 28, that the party has not sustained its burden of proving the invalidity of any patent claim in suit or if a final decision in an inter partes reexamination proceeding instituted by a third-party requester is favorable to the patentability of any original or proposed amended or new claim of the patent, then neither that party nor its privies may thereafter request an inter partes reexamination of any such patent claim on the basis of issues which that party or its privies raised or could have raised in such civil action or inter partes reexamination proceeding, and an inter partes reexamination requested by that party or its privies on the basis of such issues may not thereafter be maintained by the Office, notwithstanding any other provision of this chapter. This subsection does not prevent the assertion of invalidity based on newly discovered prior art unavailable to the third-

party requester and the Patent and Trademark Office at the time of the inter partes reexamination proceedings.

35 U.S.C. § 318. Stay of litigation

Once an order for inter partes reexamination of a patent has been issued under section 313, the patent owner may obtain a stay of any pending litigation which involves an issue of patentability of any claims of the patent which are the subject of the inter partes reexamination order, unless the court before which such litigation is pending determines that a stay would not serve the interests of justice.